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National Institute for Health Research

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Dedication to Professor Donna Lamping: It was with great sadness that the team learned of Donna's illness in 2010 and her passing in 2011 at age 58. Donna was an international expert in the field of health psychology, health status and quality of life assessment. Educated and trained in centres of excellence in Canada and the USA, she moved to the London School of Hygiene and Tropical Medicine in 1992 where she established her position as an international leader in the field. Donna was an inspiration to the team, making a major contribution to the conception, design and gold standard evaluation of the Pressure Ulcer Quality of Life (PU-QOL) studies in her role as a grant co-applicant and through PhD supervision of Claudia Rutherford (née Gorecki). We feel privileged to have worked with her and dedicate this monograph to her memory.

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Abstract

Pressure UlceR Programme Of reSEarch (PURPOSE): using mixed methods (systematic reviews, prospective cohort, case study, consensus and psychometrics) to identify patient and organisational risk, develop a risk assessment tool and patient-reported outcome Quality of Life and Health Utility measures

Jane Nixon,[1]* E Andrea Nelson,[2] Claudia Rutherford,[1] Susanne Coleman,[1] Delia Muir,[1] Justin Keen,[3] Christopher McCabe,[4] Carol Dealey,[5,6] Michelle Briggs,[7] Sarah Brown,[1] Michelle Collinson,[1] Claire T Hulme,[8] David M Meads,[8] Elizabeth McGinnis,[9] Malcolm Patterson,[10] Carolyn Czoski-Murray,[8] Lisa Pinkney,[3] Isabelle L Smith,[1] Rebecca Stevenson,[1] Nikki Stubbs,[11] Lyn Wilson[1,12] and Julia M Brown[1]

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Background: The Pressure UlceR Programme Of reSEarch (PURPOSE) consisted of two themes. Theme 1 focused on improving our understanding of individuals' and organisational risk factors and on improving the quality of risk assessments (work packages 1–3) and theme 2 focused on developing patient-reported outcome measures (work packages 4 and 5).

Methods: The programme comprised 21 individual pieces of work. Pain: (1) multicentre pain prevalence study in acute hospitals, (2) multicentre pain prevalence study in community localities incorporating (3) a comparison of case-finding methods, and (4) multicentre, prospective cohort study. Severe pressure ulcers: (5) retrospective case study, (6) patient involvement workshop with the Pressure Ulcer Research Service User Network for the UK (PURSUN UK) and (7) development of root cause analysis methodology. Risk assessment: (8) systematic

review, (9) consensus study, (10) conceptual framework development and theoretical causal pathway, (11) design and pretesting of draft Risk Assessment Framework and (12) field test to assess reliability, validity, data completeness and clinical usability. Quality of life: (13) conceptual framework development (systematic review, patient interviews), (14 and 15) provisional instrument development, with items generated from patient interviews [from (1) above] two systematic reviews and experts, (16) pretesting of the provisional Pressure Ulcer Quality of Life (PU-QOL) instrument using mixed methods, (17) field test 1 including (18) optimal mode of administration substudy and item reduction with testing of scale formation, acceptability, scaling assumptions, reliability and validity, and (19) field test 2 – final psychometric evaluation to test scale targeting, item response categories, item fit, response bias, acceptability, scaling assumptions, reliability and validity. Cost–utility: (20) time trade-off task valuations of health states derived from selected PU-QOL items, and (21) validation of the items selected and psychometric properties of the new Pressure Ulcer Quality of Life Utility Index (PUQOL-UI).

Key findings: Pain: prevalence studies – hospital and community patients experience both pressure area-related and pressure ulcer pain; pain cohort study – indicates that pain is independently predictive of category 2 (and above) pressure ulcer development. Severe pressure ulcers: these were more likely to develop in contexts in which clinicians failed to listen to patients/carers or recognise/respond to high risk or the presence of an existing pressure ulcer and services were not effectively co-ordinated; service users found the interactive workshop format valuable; including novel components (interviews with patients and carers) in root cause analysis improves the quality of the insights captured. Risk assessment: we developed a Pressure Ulcer Risk Assessment Framework, the PURPOSE-T, incorporating the Minimum Data Set, a screening stage, a full assessment stage, use of colour to support decision-making, and decision pathways that make a clear distinction between patients with an existing pressure ulcer(s) (or scarring from previous ulcers) who require secondary prevention and treatment and those at risk who require primary prevention (http://medhealth.leeds.ac.uk/accesspurposet). Quality of life: the final PU-QOL instrument consists of 10 scales to measure pain, exudate, odour, sleep, vitality, mobility/movement, daily activities, emotional well-being, self-consciousness and appearance, and participation (http://medhealth.leeds.ac.uk/puqol-ques). Cost–utility: seven items were selected from the PU-QOL instrument for inclusion in the PUQOL-UI (http://medhealth.leeds.ac.uk/puqol-ui); secondary study analysis indicated that item selection for the PUQOL-UI was appropriate and that the index was acceptable to patients and had adequate levels of validity.

Conclusions: The PURPOSE programme has provided important insights for pressure ulcer prevention and treatment and involvement of service users in research and development, with implications for patient and public involvement, clinical practice, quality/safety/health service management and research including replication of the pain risk factor study, work exploring ‘best practice’ settings, the impact of including skin status as an indicator for escalation of preventative interventions, further psychometric evaluation of PU-QOL and PUQOL-UI the measurement of ‘disease attribution.’

Funding: The National Institute for Health Research Programme Grants for Applied Research programme.

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Glossary

Algorithm The equation that enables conversion of responses on the health state classification system (i.e. the Pressure Ulcer Quality of Life Utility Index) to health state utility values.

Backing-off procedure The revision of the valuation design (in particular the corner states) to avoid implausible health states.

Construct/variable The main topic or outcome under investigation, for example quality of life.

Corner state/s When one domain only is at the most severe level and all others are at the least severe level.

Direct causal factor A factor that directly impacts the outcome (or the likelihood of the outcome).

Domain The higher-level grouping of related topics/issues that are closely associated to the outcome of interest (or variable). For example, a domain of the construct quality of life could be 'physical functioning'.

Domain level The 'response' level of the measure being considered, that is, level 1 refers to 'no bother', level 2 refers to 'a little bother' and level 3 refers to 'a lot of bother'.

Health-related quality of life A multidimensional construct that represents an individual's perception of how a given disease or medical condition and its treatment affect, at a minimum, his or her psychological, physical and social functioning.

Independent risk factor A risk factor that retains its statistical association with the outcome when other established risk factors for the outcome are included in a statistical model.

Indirect causal factor A factor that impacts the outcome (or affects its likelihood of occurrence) by changing a direct causal factor. If the direct causal factor is prevented from changing, then changes in the outcome will not be produced.

Instrument Encompasses any method used to measure the variable or construct of interest, including rating scales, questionnaires, clinical assessments and electronic devices.

Inverse corner state/s When one attribute only is at the least severe level. These states provide information on the weight of the domain.

Item Refers to a single question intended to assess or measure a particular variable. A variable is usually measured by an instrument or a scale consisting of multiple items representing aspects relevant to the particular variable.

Minimum Data Set A list of key data that should be recorded in all settings to allow comparison of patient groups.

Non-independent risk factor A risk factor that loses its statistical association with the outcome when other established risk factors for the outcome are included in a statistical model.

Patient-reported outcome A measurement of any aspect of a patient's health status that comes directly from the patient without any interpretation of the patient's response by physicians or others, about how he or she functions or feels in relation to a health condition or its therapy.

Ping-pong procedure Interview technique when eliciting preferences in which the number of years to be traded switches alternatively from high to low offers until the point of indifference is reached.

PITS A term used to denote the worst health state in which all of the domains are at the most severe level.

Pressure area A body site where pressure ulcers commonly develop; most commonly these include the sacrum, buttocks, ischial tuberosities, hips, heels, ankles and elbows.

Pressure area-related pain Pain, soreness or discomfort in any pressure area.

Pressure ulcer pain Pain, soreness or discomfort at a body site with an observable pressure ulcer.

Quality of life A multidimensional construct referring to all aspects of a person's well-being influenced by the person's perceived level of satisfaction in a variety of circumstances.

Response options The choices available to select when answering a particular question, used to quantify items. For example, 'not at all'/'a little'/'moderately'/'quite a bit'/'extremely' are response categories for the Short Form questionnaire-12 items health status instrument.

Risk factor A variable with a significant statistical association with a clinical outcome.

Subdomain A further breakdown of the domain into its constituent parts, for example 'walking' could be a subdomain of the higher-level domain 'physical functioning'.

Time trade-off A preference elicitation technique in which respondents consider how much time in a given ill-health state they are willing to trade for less time in full or perfect health.

Unattributed pressure area-related pain Pain, soreness or discomfort reported by patients on a pressure area/pressure ulcer but in which the body site is not specified/recorded.

Utility Health state utility values typically range from 1 (perfect health) through 0 (dead) to minus infinity. They are used to weight life-years to produce quality-adjusted life-year estimates for use in cost–utility analyses.

List of abbreviations

ADL	activities of daily living
AF	acceleration factor
AMED	Allied and Complementary Medicine Database
BMI	body mass index
BNI	British Nursing Index
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CRN	clinical research nurse
CSUM	condition-specific utility measure
CTRU	Clinical Trials Research Unit
CTT	classical test theory
DIF	differential item functioning
EPUAP	European Pressure Ulcer Advisory Panel
EQ-5D	European Quality of Life-5 Dimensions
EQ-5D-3L	European Quality of Life-5 Dimensions three-level version
FDA	Food and Drug Administration
HRQoL	health-related quality of life
HTA	Health Technology Assessment
ITC	item–total correlation
LANSS	Leeds Assessment of Neuropathic Symptoms and Signs
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPUAP	National Pressure Ulcer Advisory Panel
OR	odds ratio
PABAK	prevalence-adjusted bias-adjusted kappa
PI	principal investigator
PPI	patient and public involvement
PRO	patient-reported outcome
PUPPs	Pressure Ulcer Prevention Pathways
PU-QOL	Pressure Ulcer Quality of Life
PUQOL-UI	Pressure Ulcer Quality of Life – Utility Index
PURAF	Pressure Ulcer Risk Assessment Framework
PURPOSE	Pressure UlceR Programme Of reSEarch
PURPOSE-T	Pressure Ulcer Risk Primary Or Secondary Evaluation Tool
PURSUN UK	Pressure Ulcer Research Service User Network UK
QALY	quality-adjusted life-year
QAS-99	Question Appraisal System
RAND/UCLA	Research and Development, University of California in Los Angeles
RMT	Rasch measurement theory
SD	standard deviation
SF-6D	Short Form questionnaire-6 Dimensions
SF-12	Short Form questionnaire-12 items
TTO	time trade-off
TVNS	tissue viability nurse specialist
VAS	visual analogue scale
WOK	Web of Knowledge

Plain English summary

Background

Pressure ulcers (sometimes called bedsores or pressure sores) are areas of damaged skin and tissue. They are usually caused by limited mobility and often occur as a complication of another illness or injury. They can lead to extended hospital stays, reduced quality of life and, rarely, death.

Pressure ulcer programme of research

The Pressure UlceR Programme Of reSEarch (PURPOSE) comprises two themes: risk assessment and quality of life. Each theme was split into work packages.

Theme 1: risk assessment

Work package 1: pain

We found that many patients reported pressure ulcer and pressure area pain and that pressure area pain is a pressure ulcer early warning sign. We demonstrated the importance of assessing and reacting to pressure ulcer and pressure area pain.

Work package 2: severe pressure ulcers

We investigated the development of particularly severe pressure ulcers and found that they are more likely to occur in environments where:

- clinicians fail to listen to patients and carers
- clinicians fail to recognise and react to signs that patients are at risk of, or already have, pressure ulcers
- services are not organised effectively.

Work package 3: risk assessment

Risk assessment tools are used to identify people at risk of pressure ulcers. We have developed and tested an up-to-date risk assessment tool.

Theme 2: quality of life

Work package 4: Pressure Ulcer Quality of Life

General health questionnaires may not capture what is important to people with a specific health problem. We have developed and tested a pressure ulcer questionnaire to assess issues that are important to patients.

Work package 5: pressure ulcer cost–utility

To determine whether or not new treatments are good value for money, we have developed a pressure ulcer-specific economic measure to evaluate the cost-effectiveness of pressure ulcer treatments more accurately.

Patient and public involvement

The Pressure Ulcer Research Service User Network (PURSUN UK) was established as part of PURPOSE. PURSUN UK is made up of service users with personal experience of pressure ulcers or pressure ulcer risk. Members have contributed throughout the programme and continue to be involved in research.

Scientific summary

Background

Pressure ulcers are a widespread, cross-speciality problem. They represent a major burden to patients and carers, having a detrimental effect on health-related quality of life (HRQoL), and are costly to the NHS.

Programme aims

The Pressure UlceR Programme Of reSEarch (PURPOSE) was developed by a clinical–research collaborative. The work was organised into two themes with the following aims:

1. theme 1: to reduce the impact of pressure ulcers on patients through early identification of patients at risk of developing pressure ulceration
2. theme 2: to reduce the impact of pressure ulcers on patients through the development of methods to capture patient-reported HRQoLs and health utilities for routine clinical use and future research.

Patient and public involvement

We set up the Pressure Ulcer Research Service User Network (PURSUN UK) and with members have developed innovative patient and public involvement (PPI) methods to underpin programme development, delivery and dissemination. Examples of innovative activity include adaptation of the Patient Learning Journey preparation model for use in a research context; use of role play and video to facilitate PPI in the interpretation of qualitative data; integration of PPI into consensus methods; integration of service user narratives into dissemination materials; and the development of a live interview model to facilitate meaningful PPI at professional conferences and training events.

Rationale and aims

Theme 1 focused on improving our understanding of individuals' and organisational risk factors and on improving the quality of risk assessments (work packages 1–3). Theme 2 focused on developing patient-reported outcome (PRO) measures (work packages 4 and 5).

Work package 1: pain

Patients have reported that pressure ulcer pain is their most distressing symptom, that pain at 'pressure areas' was experienced before pressure ulcer manifestation and that their reports of pain are ignored by nurses. The primary aim of the research was to determine the extent of pressure area and pressure ulcer pain and explore the role of pain as a predictor of category 2 (and above) pressure ulcers in acute hospital and community populations.

Work package 2: severe pressure ulcers

There is good evidence that pressure ulcer risks are associated with patient health status but also suggestive evidence that the organisation of care can influence the risks. We aimed to describe and explain the ways in which the organisation of treatment and care influences the development of severe pressure ulcers and identify ways to improve root cause analyses.

Work package 3: risk assessment

Increasing evidence makes it timely to update pressure ulcer risk assessment and how to prompt an escalation of interventions for secondary prevention and treatment. The primary aim of the research was to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of an evidence-based Risk Assessment Framework to guide decision-making about the risk of developing pressure ulceration and the risk of progression to more severe ulceration.

Work package 4: quality of life

Patient-reported outcome instruments are used to inform patient care and compare treatment effectiveness. The principal aim of this work package was to develop a PRO measure of HRQoL specifically for people with pressure ulcers: the Pressure Ulcer Quality of Life (PU-QOL) instrument.

Work package 5: cost–utility

Cost–utility analysis is the gold standard for economic evaluation and, in some therapeutic areas, condition-specific utility measures are developed to provide assessment of the impact of conditions and a measure of treatment benefit. The aim of the study was to create a preference-based index (Pressure Ulcer Quality of Life – Utility Index; PUQOL-UI) that could be used to generate utility values suitable for use in cost–utility-based economic evaluations of pressure ulcer interventions.

Methods

The programme comprised 21 research studies, methodological substudies and projects as follows:

1. Pain: (1) multicentre acute hospital pain prevalence study; (2) multicentre community pain prevalence study incorporating (3) a comparison of case-finding methods; and (4) multicentre prospective cohort study.
2. Severe pressure ulcers: (5) retrospective case study; (6) patient involvement workshop with PURSUN UK; and (7) development of root cause analysis methodology.
3. Risk assessment: (8) systematic review; (9) consensus study; (10) conceptual framework development and theoretical causal pathway; (11) design and pretesting of the draft Risk Assessment Framework; and (12) field test to assess reliability, validity, data completeness and clinical usability.
4. Quality of life: (13) conceptual framework development (systematic review, patient interviews); (14 and 15) provisional instrument development; (16) pretesting of the provisional PU-QOL instrument using mixed methods; (17) field test 1 including (18) an optimal mode of administration substudy and item reduction with testing of scale formation, acceptability, scaling assumptions, reliability and validity; and (19) field test 2 – final psychometric evaluation to test scale targeting, item response categories, item fit, response bias, acceptability, scaling assumptions, reliability and validity.
5. Cost–utility: (20) time trade-off task valuations of health states derived from selected PU-QOL items and (21) validation of the items selected and the psychometric properties of the new PUQOL-UI.

Key findings

Theme 1

Work package 1: pain

Pressure area-related pain prevalence was 16.3% (327/2010) in the hospital population. Of 1769 hospital patients with no observable pressure ulcers, 12.6% (233) reported pressure area-related pain. The prevalence of pressure area-related pain in patients with pressure ulcers was 43.2% (104/241) in hospital patients and 75.6% (133/176) in community patients. A detailed pain assessment of 197 patients identified pressure area-related pain on skin areas assessed as normal as well as on pressure ulcers. The distribution of pain intensity was similar for all grades and both inflammatory and neuropathic pain were observed. The community trusts utilised different methods of case ascertainment and different pressure ulcer prevalence rates were observed (locality 1 = 0.77 and locality 2 = 0.40 per 1000 adult population).

The prospective cohort study of 632 acutely ill hospital and community patients identified significant evidence that the presence of pain at a skin site is an independent predictor for developing a category 2 or above pressure ulcer in four multivariable models as follows: (1) a priori logistic regression, (2) overdispersion logistic regression model and (3) an Accelerated Failure Time model for analyses conducted on a patient level, and (4) a multilevel logistic regression model for the analysis conducted on a skin-site level.

Work package 2: severe pressure ulcers

For seven of eight patients the best explanation of the evidence was that the general organisational context played a significant role in severe pressure ulcer development. In four accounts, specific events contributed to development. One patient's ulcer was deemed unavoidable. Severe pressure ulcers were more likely to develop in contexts in which clinicians failed to listen to patients/carers or recognise/respond to high risk or the presence of an existing pressure ulcer and services were not effectively co-ordinated. Service users found the interactive workshop format and the use of a 'simulated patient' account valuable. Including novel components (interviews with patients/carers) and sensitivity to the contexts within which health professionals work in root cause analysis can improve the quality of the insights captured.

Work package 3: risk assessment

1. The systematic review identified 15 risk factor domains and 46 subdomains, with three primary risk factor domains of mobility/activity, skin/pressure ulcer status and perfusion (including diabetes). It suggests that no single factor can explain pressure ulcer development.
2. The consensus study facilitated agreement of risk factors/assessment items for the Minimum Data Set (including immobility, pressure ulcer and skin status, perfusion, diabetes, skin moisture, sensory perception and nutrition), and draft Risk Assessment Framework [subsequently named Pressure Ulcer Risk Primary or Secondary Evaluation Tool (PURPOSE-T)] development.
3. The new conceptual framework incorporates five key components [(1) mechanical boundary conditions, (2) physiology and repair, (3) mechanical properties of tissue, (4) geometry of tissue/bone and (5) transport and thermal properties] and their impact on internal strains, stresses and damage thresholds. The theoretical causal pathway identifies direct, key indirect and other potential causal factors for pressure ulcer development.
4. The design and pretesting of the draft PURPOSE-T led to improved usability over the course of three pretest sessions, demonstrated by increased data completeness and appropriate pathway allocation.
5. The field test demonstrated that inter-rater and test–retest agreement for the PURPOSE-T was 'very good' (kappa) for the assessment decision overall. The inter-rater and test–retest percentage agreement for 'problem/no problem' ranged from 79.1% to 94.2% for the main risk factors. Convergent validity demonstrated moderate to high associations. Field notes highlighted positive and problem aspects in relation to using the PURPOSE-T in the clinical environment.
6. A follow-up meeting of experts and service users allowed consideration of the pain cohort study results and led to revisions of the PURPOSE-T and inclusion of pressure area-related pain.
7. The final PURPOSE-T has the following features: Minimum Data Set, screening stage to target assessment towards those in need, full assessment stage, use of colour to weight risk factors, and decision pathways that distinguish between patients with an existing pressure ulcer or scarring who require secondary prevention and treatment and those at risk who require primary prevention.

Theme 2

Work package 4: quality of life

Our conceptual model includes four HRQoL domains [(1) symptoms, (2) physical functioning, (3) psychological well-being, and (4) social participation] divided into 13 subdomains. The final PU-QOL instrument consists of 10 scales to measure pain, exudate, odour, sleep, vitality, mobility/movement, daily activities, emotional well-being, self-consciousness and appearance, and participation. We established that self-administration is not suitable for hospital inpatients with pressure ulcers and it is intended for administration following a user manual. Respondents rate the amount of 'bother' attributed on a 3-point scale. The final PU-QOL instrument mostly satisfies psychometric criteria for acceptability, reliability and validity.

Work package 5: cost–utility

Seven items were selected from the PU-QOL instrument for inclusion in PUQOL-UI on the basis of best practice psychometric and Rasch methods. Of the large number of potential health states constructed from the items and response option variants, 52 were valued by the general population, with the remaining health state values being predicted using ordinary least squares and random-effects regression models. Although both models exhibited satisfactory predictive power and acceptably low levels of error, the random-effects model is recommended for use. The secondary study analysis indicated that item selection for the PUQOL-UI was appropriate and acceptable to patients and that items had adequate levels of validity.

Conclusions

The PURPOSE programme supported the development of a network of 30 acute and community NHS trusts and accrual of a total of 6735 patients to the National Institute for Health Research portfolio. The PURPOSE programme has provided important insights for pressure ulcer prevention and treatment and the involvement of service users in research and development, with implications for PPI, clinical practice, quality/safety/health service management and future research.

Implications for patient and public involvement in research

1. Patient and public involvement requires explicit commitment to involving services users and their perspectives throughout every aspect of the research process.
2. Presenting research data in live and interactive formats can make the interpretation process more engaging and accessible to service users and can support meaningful dialogue between service users and professionals.

Implications for clinical practice development

1. Front-line health-care professionals should respond to patient symptoms including pain (soreness and discomfort), alterations to intact skin and category 1 pressure ulcers and instigate/escalate care provision.
2. Patients with pressure ulcers should have pain assessment, including type of pain, to inform treatment.
3. In circumstances in which clinicians do not have the skills necessary to address needs, patients should be referred to appropriate colleagues.
4. Some clinicians blamed patients for the development of severe pressure ulcers. In circumstance in which the provision of effective pressure ulcer prevention interventions is impacted by a patient's mental capacity or physical disability, advice (consultation) should be sought from colleagues with appropriate multidisciplinary specialist expertise and a problem-solving approach adopted.
5. Development of an electronic version of PURPOSE-T in health-care settings would facilitate large-scale multivariable modelling and the refinement of PURPOSE-T.
6. The implementation of key research findings may be facilitated through the use of the active monitoring model of care – Pressure Ulcer Prevention Pathways (PUPPs) – which incorporates risk assessment using the PURPOSE-T (including skin status and pain), the allocation of patients to primary and secondary prevention pathways and active monitoring of individual patients' skin responses to preventative interventions. It details required actions and escalation in response to deterioration and pressure ulcer development.

Implications for quality, safety and health service management

1. To maximise learning, root cause analysis could be extended in two ways:

    i. interview patients and carers to capture their accounts of events
    ii. increase awareness of the possibility that staff are working in contexts in which risky practices are tolerated and be able to assess whether or not this is the case.

2. It is important to co-ordinate services effectively so that pressure ulcer risks are communicated to everyone involved (patients, carers, all members of the multidisciplinary team).
3. Service reconfiguration/ward reorganisation planning needs to ensure continuity of clinical leadership and oversight/delivery of clinical care to high-risk patients.
4. A standardised case ascertainment method in the community setting should be developed.

Implications for future research

Pain

1. Replication of the pain cohort study is required.
2. The impact of including pain as an indicator for the escalation of preventative interventions requires investigation.

Severe pressure ulcers

1. The severe pressure ulcer study is the first of its kind and the findings should be confirmed by further empirical research.
2. There may be merit in studying 'best practice' settings to better understand how patients' and organisational risks are identified and effectively acted on.

Risk assessment

1. Development of objective measurement methods of mechanical boundary conditions, individual susceptibility and tissue tolerance, and early indicators of damage.
2. Further evaluation of the PURPOSE-T is required including sensitivity and specificity in different patient populations, impact on decision-making/processes of care and effectiveness in reducing pressure ulcer incidence in practice.
3. The pressure ulcer risk factor Minimum Data Set should be incorporated into future research.
4. Development of appraisal methods for risk factor research.
5. Development of a lay version of PURPOSE-T that can be used by patients and carers to facilitate self-assessment.
6. The impact of including skin status as an indicator for the escalation of preventative interventions requires investigation.

Quality of life

1. The PU-QOL instrument requires further evaluation through assessment of responsiveness to provide evidence to support score interpretation and to explore utility in routine practice.
2. The PU-QOL can be used in pressure ulcer research on the proviso that studies undertake parallel psychometric analysis to assess the performance of the scales in future samples.
3. The PU-QOL instrument requires translation and validation for international utilisation.

Cost–utility

1. The PUQOL-UI can be used in pressure ulcer prevention/treatment trials to enable cost–utility analyses.
2. Further research is required to determine the responsiveness of the PUQOL-UI.
3. Further research is required to establish the benefits of the PUQOL-UI (and other condition-specific utility measures) over generic utility measures; this must take into consideration the impact that condition-specific utility measures may have on decision-making and efforts to achieve allocative efficiency.
4. Further research is required to determine the extent to which patients completing HRQoL measures consider (and are able to consider) 'disease attributable' impact only.

Access to PURPOSE tools and instruments

1. PURPOSE-T: http://medhealth.leeds.ac.uk/accesspurposet (accessed July 2015).
2. PUPPs: http://medhealth.leeds.ac.uk/accesspurposet (accessed July 2015).
3. PUQOL: http://medhealth.leeds.ac.uk/puqol-ques (accessed July 2015).
4. PUQOL-UI: http://medhealth.leeds.ac.uk/puqol-ui (accessed August 2015).

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Chapter 1 Background

Introduction

Pressure ulcers are defined as 'localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear' (p.16).[1] They are a widespread[2–4] and costly health-care issue.[5–8] Pressure ulcers represent a major burden to patients and carers and have a detrimental effect on patients' quality of life.[9,10]

For the past two decades pressure ulcers have been identified in successive Department of Health policies as a key quality indicator,[11,12] with associated guidelines for prevention[13,14] and treatment.[15] There have been widespread changes in clinical practice during this period including the introduction of systematic risk assessment processes, investment in pressure-relieving mattresses, and quality improvement initiatives. However, reflecting the belief that the development of pressure ulcers remains an indicator of service quality that impacts on patients and health-care costs, more recently the Department of Health have set out the ambitious aim of eliminating all avoidable pressure ulcers in NHS-provided care,[16] developed a Commissioning for Quality and Innovation Payment Framework to facilitate this,[17] identified pressure ulcers as a high-impact action for nursing and midwifery[18] and incorporated them into the national Operating Framework.[19] Despite the prominence and profile afforded the problem, the research basis to inform practice in this area is limited, partly because we do not understand the clinical and organisational risks sufficiently well and partly because of the dearth of high-quality randomised controlled trials of preventative and treatment interventions.[14,15,20] Our programme of work was established to provide the foundation for the development of an evidence base for practice through improved identification of patients at risk of pressure ulcer development and improved methods of evaluating outcomes that are important to patients.

In 2004, UK costs associated with pressure ulcer prevention and treatment were estimated to be £1.4–2.1B annually, equivalent to 4% of total NHS expenditure,[5] because of increased length of hospital stay, hospital admission, community nursing, treatments (reconstruction surgery/mattresses/dressings/technical therapies) and complications (serious infection). Litigation is also a burden on NHS resources and is predicted to increase because of both general societal trends and changes in the law, which has led to investigation of severe pressure ulcers by government agencies to detect institutional and professional neglect of vulnerable adults.[21,22] The NHS focus on pressure ulcer prevention is mirrored elsewhere. In the USA, for example, health insurance companies have incentivised prevention through widespread changes to reimbursement policies. Hence, health-care providers are liable for the treatment costs arising from pressure ulcers that develop during care (organisation-acquired avoidable pressure ulcers).[17]

Pressure ulcer classification

Numerous classification systems have been developed to categorise the severity of pressure ulcers. Before the start of the programme grant (in 2008) the two most commonly used systems classified pressure ulcers through four levels (1–4) of 'stage' or 'grade'.[15–17] The descriptors ranged from non-blanching erythema of intact skin at level 1 (stage 1/grade 1) to full-thickness tissue loss at the most severe level (stage 4/grade 4).[23–25] In 2009 the American National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP) developed joint guidelines and a revised classification system.[1] The two main differences were the use of the term 'category' (to distance the description from the ordinal properties assumed by the use of stage and grade) and the inclusion of two new descriptors: 'unstageable' and 'deep tissue injury'. In the following chapters we have adopted the use of the NPUAP/EPUAP (2009) classification and use the term 'category' (with Arabic numerals rather than roman for ease of reading) to classify pressure ulcers in general reference to the literature and the terms 'stage' or 'grade' when reporting directly from individual studies, to accurately report the

classification system used by the authors. In addition, the terms 'superficial' and 'severe' pressure ulcers are used to summarise pressure ulcer severity. A superficial ulcer is a category 2 ulcer and the term 'severe' is used to describe category 3, category 4 and unstageable pressure ulcers.

For clarification, the programme excluded consideration of ulcers caused by medical devices (e.g. nasogastric tubes, surgical drains, oxygen masks, urinary catheters, cannulas and prosthetic limbs).

Summary of the programme of research

The Pressure UlceR Programme Of reSEarch (PURPOSE) was developed by a clinical/academic research collaborative to address a number of research questions. The areas of work were organised into two themes with the following aims:

1. theme 1 – to reduce the impact of pressure ulcers on patients through:

    i. early identification of patients at risk of developing pressure ulceration and
    ii. improved identification and investigation of patients at risk of progression to severe pressure ulceration

2. theme 2 – to reduce the impact of pressure ulcers on patients through the development of methods to capture patient-reported health-related quality of life (HRQoL) and health utilities for routine clinical use and in clinical trials.

Theme 1 focused on improving our understanding of risk factors and risk assessment and consisted of three work packages with the following objectives:

- work package 1 – pain: to determine the extent of pressure area and pressure ulcer pain and explore the role of pain as a predictor of category 2 and above pressure ulcers in acute hospital and community populations
- work package 2 – severe pressure ulcers: to identify individual and organisational factors that contribute to the development of severe pressure ulcers and develop a critical incident/adult neglect investigation methodology for their review
- work package 3 – pressure ulcer risk assessment: to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of an evidence-based Risk Assessment Framework to guide decision-making about the risk of developing pressure ulceration and the risk of progression to more severe ulceration.

Theme 2 had a focus on the development of patient-reported outcome (PRO) measures and consisted of two work packages with the following objectives:

- work package 4 – pressure ulcer quality of life: to determine outcomes important to patients who develop pressure ulcers and develop a psychometrically rigorous PRO measure that is reliable and valid and suitable for use in the NHS.
- work package 5 – pressure ulcer quality of life utility instrument: to create a preference-based index that could be used to generate utility values suitable for use in cost–utility-based economic evaluations of pressure ulcer prevention and treatment interventions.

Both themes 1 and 2 were planned to progress in parallel. Within each theme, planning ensured that the early work contributed to later studies. Work packages 1 and 2 contributed to work package 3, and work package 4 contributed to work package 5 (*Figure 1*). In addition, within each work package we utilised a range of research methods in sequential phases including (for example) systematic reviews, prevalence studies, prospective cohort study, case study consensus methods, psychometric evaluation and time trade-off (TTO) task valuations of health states (*Table 1*).

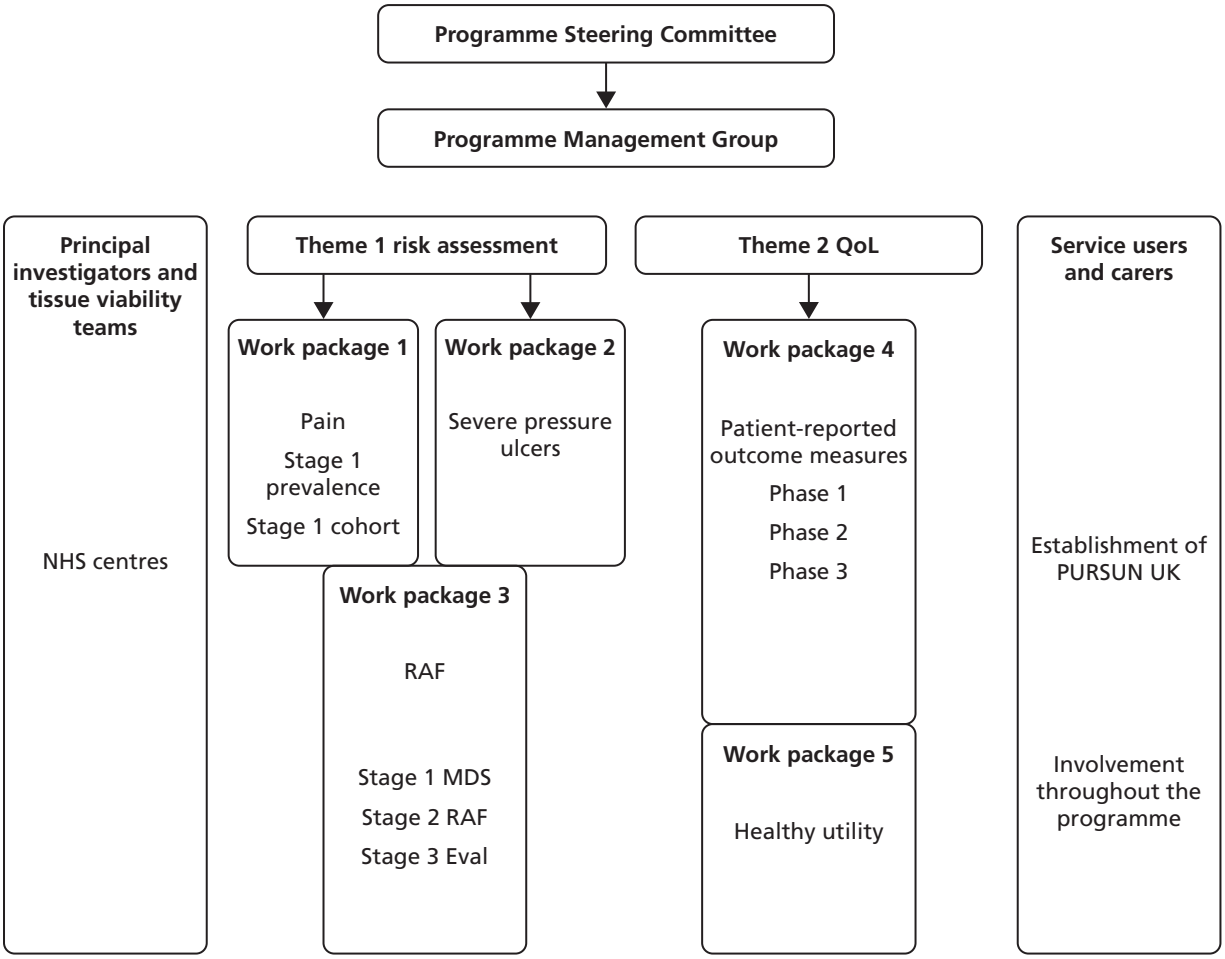

FIGURE 1 Outline of the programme. Eval, evaluation; MDS, minimum data set; PURSUN UK, Pressure Ulcer Research Service User Network UK; QoL, quality of life; RAF, Risk Assessment Framework.

TABLE 1 Summary of PURPOSE research and associated projects

WP1 – pain (see *Chapter 3*)	WP2 – severe pressure ulcers (see *Chapter 4*)	WP3 – risk assessment (see *Chapter 5*)	WP4 – pressure ulcer quality of life (see *Chapter 6*)	WP5 – pressure ulcer quality of life utility instrument (see *Chapter 7*)
• Hospital pain prevalence • Community pain prevalence • Pain cohort • Community PU prevalence methodology substudy[a]	• Main study • PURSUN UK interpretation workshop[a] • Implementation project (including PURSUN UK[a])	• Systematic review • Consensus study (including PURSUN UK[a]) • Conceptual framework[a] • Pretest (including PURSUN UK[a]) • Field test	• Systematic review of existing measures[a] • Systematic review of pain descriptors[a] • Conceptual framework • Pretest • Field test 1 (including traditional vs. Rasch psychometrics[a]) • Administration mode substudy[a] • Field test 2	• Valuation survey (including PURSUN UK[a]) • Validation substudy (including PURSUN UK[a])

PU, pressure ulcer; PURSUN UK, Pressure Ulcer Research Service User Network UK; WP, work package.
a Methodological and patient and public involvement work undertaken in addition to the work in the original grant application plan.

Development of the research programme

During the course of the programme, delivery enhancements to the original proposal were made including NHS capacity development, patient and public involvement (PPI) and additional reviews and methodological research.

NHS research capacity development

Patient populations in pressure ulcer research are characterised by high levels of comorbidity, and are distributed across multiple care environments. This poses challenges in study design, recruitment and follow-up. The programme grant application was underpinned by a strong network of NHS collaborators across 13 acute and community NHS trusts (see *Figure 1*). During the programme of research (2008–13) this was further developed through support from the West Yorkshire Comprehensive Local Research Network, National Institute for Health Research (NIHR) portfolio adoption and incorporation onto the Dermatology and Primary Care portfolios, facilitating access to service support costs through the NIHR Comprehensive Local Research Networks and the participation of 30 acute and community NHS trusts (see *Appendix 1* and *Acknowledgements*).

Patient and public involvement in pressure ulcer research

In addition, our original PPI plan was limited and this was significantly enhanced. We established a partnership with service users through the set-up of the UK Pressure Ulcer Research Service User Network (PURSUN UK) (see *Figure 1* and *Chapter 2*). Service-user involvement underpinned our development and delivery of the programme of research as well as the dissemination and identification of ongoing research priorities. Indeed, PURSUN UK made a major contribution to the design, conduct and interpretation of the research, with the use of innovative involvement activities (see *Table 1* and *Chapter 2*).

Additional reviews and methodological research

The original programme of work was enhanced through an additional two systematic reviews and five methodological substudies (see *Table 1*) addressing methodological issues with wider relevance to the applied health research field.

Structure of this report

Within each work package there are a number of components, including systematic reviews, primary research and methodological substudies. In total, 21 pieces of work have been undertaken, as illustrated in *Table 1*.

The monograph is structured as follows:

- *Chapter 2* provides an overview of the PPI activities, innovation and support
- *Chapters 3–7* present the rationale and research (including substudies), PPI and implementation components of each work package
- *Chapter 8* describes the wider benefits accrued through the PURPOSE programme award and 5-year investment period and summarises the key findings and their implications for practice, PPI, policy and research.

Chapter 2 Patient and public involvement

Chapter written by Delia Muir, Susanne Coleman, Lyn Wilson, Nikki Stubbs, Justin Keen, Elizabeth McGinnis and Jane Nixon.

Background

The importance of PPI within PURPOSE was recognised at the start of the programme. PPI in pressure ulcer research has not been strong to date and the project team identified an opportunity to address this through the programme. PPI can contribute at all stages of the research process, from commissioning and priority setting through to dissemination and implementation.[26–28] There is a danger, however, that PPI activities can become tokenistic, particularly when driven by 'top-down' policy initiatives rather than a genuine desire to learn from, and with, service users.[29]

In recent years there has been a growth in PPI literature;[26] however, inconsistencies in reporting and the variety of research methodologies covered by this literature make comparing studies and establishing quality challenging.[26,27] Recent reviews do highlight some general good practice principles. Shippee and colleagues[30] describe four key components of involvement: (1) service user initiation (i.e. preparation, negotiating roles, establishing shared interests and goals), (2) building reciprocal relationships between service users and researchers (i.e. establish service users as valued members of the team rather than an optional addition), (3) co-learning (i.e. development of both service users and researchers) and (4) feedback (i.e. ongoing, iterative evaluation of PPI processes). This review also highlights the importance of involvement starting as early as possible in the research process. In addition, advocates of the co-production approach (used mainly in a service design and delivery context) highlight the need for peer support networks; to recognise and build on people's strengths; and to build communities.[31]

There is a paucity of literature related specifically to PPI in pressure ulcer research. The only other pressure ulcer PPI initiative that we are aware of is the James Lind Alliance Pressure Ulcer Partnership. This ran in parallel to this programme and focused on setting future research questions rather than on involvement in carrying out that research (see *Supporting further research* for additional information).

The PURPOSE project team set out to develop mechanisms for working in partnership with service users, to have a positive impact on the research methods and outputs for all strands of the programme. In line with the principles set out above, we also wanted to ensure that involvement would be a positive and rewarding experience for the individuals taking part.

Challenges

In the early stages of the programme PPI proved challenging. The project team tried to identify individuals with experience of pressure ulcers or people managing the risk of pressure ulceration (e.g. people with chronic conditions that limit mobility or people who have experienced periods of very acute illness). During the first year, two service users were identified (through clinical members of the project team) and agreed to be members of the PURPOSE steering committee. Finding more people proved difficult for a number of reasons. First, there was no infrastructure to support PPI in this field, unlike in some other areas that have established PPI networks that can support recruitment to research and offer guidance on working with particular populations. Some health and social care charities also support research and promote PPI activities. However, pressure ulcers are a cross-specialty problem; they are secondary to other serious illnesses/conditions and do not fit easily into existing national/charitable structures.

Despite efforts to recruit through generic PPI networks, our only success in identifying service users was through the project team's clinical contacts. This approach raised some ethical considerations. There were concerns that service users might feel obliged to become involved to 'repay' good care or for fear of future care being affected. It was also felt that there needed to be a clear distinction between 'caring for patients' and 'working with service users'. Clinical members of the team recruiting and supporting their own patients could potentially blur these boundaries and create unequal relationships within the team. This was a consideration when developing a PPI recruitment strategy for the programme.

Another challenge was provided by the complex health needs of many people with experience of pressure ulcers or pressure ulcer risk. As pressure ulcers affect people with serious long-term conditions or acute illness/injury, many service users with relevant experience may be unable to take part in traditional involvement activities.

To address these challenges, a PPI officer post was created. The aim of this post was to develop a pressure ulcer-focused service user network, which would both facilitate PPI throughout the programme and build PPI capacity within pressure ulcer research more generally.

The Pressure Ulcer Research Service User Network UK

The Pressure Ulcer Research Service User Network UK was established in 2010 and now has 18 members. The network is made up of service users and carers with personal experience of pressure ulceration and/or risk of pressure ulceration. Members have been identified through:

- local, generic PPI groups/networks
- snowball recruitment, whereby existing PURSUN UK members contact friends, colleagues or family members
- advertising meetings and events in the local media and via e-mail networks
- engaging with charities that focus on a topic related to pressure ulcer risk, such as conditions that limit mobility, for example the Multiple Sclerosis Society and Spina bifida, Hydrocephalus, Information, Networking, Equality (SHINE)
- social media (@PURSUN_UK)
- the distribution of PURSUN UK leaflets alongside recruitment of study participants
- tissue viability nurse specialists.

Concerns about clinical members of the research team approaching their own patients, thereby blurring roles and boundaries, have been addressed by the introduction of the PPI officer as a neutral party. Nurses in practice hand out information about PURSUN UK and service users then have the option to contact the PPI officer for further discussions and induction to the network if desired.

The Pressure Ulcer Research Service User Network UK (www.pursun.org.uk) has a minimum of two management meetings a year at which a core group of the most active members consider the direction of the network, the terms of reference, recruitment, the website and other network materials. Research involvement opportunities are sent out via the mailing list as they arise, for example invitations to help interpret data, become co-authors or input into the study methods.

All members of PURSUN UK are prepared for involvement through a minimum of one induction meeting with the PPI officer (either face-to-face or by telephone). During this meeting service users are encouraged to discuss the skills and experience that they bring to the group, as well as any support that they may need. The remit of PURSUN UK is also discussed along with practical issues such as payment of fees and expenses. Ongoing support is provided based on the individual needs of each member. Many of the core group have also been through a more in-depth process of preparation based on the Patient Learning Journey model.[32] The Patient Learning Journey model was originally developed by the Leeds Institute for

Medical Education as a way of preparing service users for involvement in the education of health professionals. The model was adapted for use in a research context, keeping the original Patient Learning Journey principles of sharing stories with other service users in a safe, facilitated environment and working together to identify themes within those experiences. Participants are also encouraged to think about which aspects of their stories they feel happy sharing with professionals and how best to communicate key messages. This novel approach to research preparation aims to help service users recognise the expertise that they have developed through their personal experiences. It also helps with group forming, encouraging empathy and peer support. Further development opportunities have been sought for members where possible, such as conference attendance and local research training. Offering a range of development opportunities has been useful: some members have travelled to large, national conferences whereas others have found shorter, local events or one-to-one meetings more manageable.

Pressure UlceR Programme Of reSEarch involvement activities

Between 2008 and 2010, PPI was limited by our ability to recruit service users. Following the establishment of PURSUN UK in late 2010, involvement activities increased across the programme. Furthermore, the methodology and focus of each work package have guided the nature of involvement. An overview of PPI activities at different stages of the programme of research is given in the following sections. Involvement in individual PURPOSE studies is also discussed in subsequent chapters.

Programme management

The PURPOSE steering committee includes two service user members. This led to the identification of the need for further PPI not only in the PURPOSE programme but also in the field of pressure ulcer research more generally. This recommendation was supported by the steering committee and led to the decision to appoint a PPI officer. A service user was involved in the recruitment process for the PPI officer post, including being a member of the interview panel.

Protocol and patient information leaflet development

Members of PURSUN UK have formally reviewed all of the PURPOSE study protocols via the PURPOSE steering committee. In addition, PURSUN UK members have made more detailed contributions to the design of the risk assessment (see *Chapter 5*) and Pressure Ulcer Quality of Life – Utility Index (PUQOL-UI) (see *Chapter 7*) studies. This has been through contributing to study protocols and advising on the development of patient information leaflets.

Data interpretation

The results of the pain studies (see *Chapter 3*) have been presented to PURSUN UK. Members have helped to put the pain results in context from a service user perspective and consider next steps for the research. They also worked with the project team to interpret qualitative data from the severe pressure ulcer study (see *Chapter 4*). This was achieved through a workshop utilising video and role play to make the interpretation process engaging and accessible for service users with little or no experience of data analysis and interpretation. This workshop is described in more detail in *Chapter 4* (see *Patient and public involvement*).

Staff training

Case studies based on the real experiences of PURSUN UK members were developed. These were then used as part of the Pressure Ulcer Risk Primary or Secondary Evaluation Tool (PURPOSE-T; a pressure ulcer risk assessment tool) pretest training sessions with nurses (see *Chapter 5*, *Phase 3: development of a new conceptual framework and theoretical causal pathway for pressure ulcer development*). This allowed nurses to apply the tool to authentic case studies, in a safe learning environment.

Instrument development

Pressure Ulcer Research Service User Network UK has had considerable input into developing PURPOSE-T, with particular focus on making the tool acceptable for patients in practice. Its involvement was integrated within the consensus methodology and had a direct influence on the items included in the tool. This is discussed further in *Chapter 5*. Members also reviewed the Pressure Ulcer Quality of Life (PU-QOL) instrument (see *Chapter 6*), providing feedback about clarity, comprehension, design, layout and item wording. This process led to some modifications to the PU-QOL instrument (e.g. clarification of instructions, revisions to the wording of some items). Members with experience of living with a pressure ulcer have also been involved in developing the PUQOL-UI (see *Chapter 7*). This involved giving feedback on the questionnaire through 'think out loud' interviews and document review.

Dissemination and knowledge transfer

Three members of PURSUN UK are currently contributing to a paper in which their real-life narratives are used to illustrate findings from the pain studies and emphasise the relevance to clinical practice. They will be co-authors on the paper. Video podcasts are also being developed with service users. Their stories will be combined with input from clinicians and used to highlight key messages from the programme. The videos will be available online.

Implementation

Members of PURSUN UK reviewed the user manual for the PU-QOL instrument. One member is also involved in piloting a new method for investigating the development of severe pressure ulcers in practice (following on from the work described in *Chapter 4*).

Wider impact of the Pressure Ulcer Research Service User Network UK

In addition to PPI throughout the programme, PURSUN UK has begun to impact the wider tissue viability and PPI communities, as described in the following sections.

Professional development activities

Members of PURSUN UK have been invited to speak about their experiences at several events. Locally, this has included training for tissue viability link nurses, presenting to PURPOSE principal investigators, speaking at the launch of the NIHR Bradford Wound Prevention & Treatment Healthcare Technology Co-operative and working with medical students. Nationally, members have presented at the Tissue Viability Society conference, tissue viability education events and the INVOLVE (a national PPI advisory group) conference.

We have developed an effective model for presenting service users' experiences in which the PPI officer interviews a member of PURSUN UK in front of a live audience. This provides an alternative to a traditional presentation for people who do not feel confident presenting personal experiences in that way. This model has received very positive feedback from both audiences and the service users involved. We have found that real-life stories are extremely powerful and can create a common focus for professionals from a variety of backgrounds.

Collaboration with industry

Medical devices play an important role in pressure ulcer prevention and treatment. With this in mind, PURSUN UK has collaborated with industry partners on projects such as education days and product development workshops. This collaboration has helped to diversify the involvement opportunities offered to PURSUN UK members and has been useful in terms of members' personal development, as it has given people an insight into another aspect of tissue viability research. This work has also generated some funds for PURSUN UK, moving the network towards a sustainable model post PURPOSE.

Supporting further research

One member of PURSUN UK is a co-applicant on PRESSURE 2 [a NIHR Health Technology Assessment (HTA) programme-funded trial comparing two mattresses; http://medhealth.leeds.ac.uk/info/423/skin/1717/pressure_2 (accessed 31 August 2015)]. The wider network both helped to develop this trial and continues to be involved with it. PURSUN UK has also been a partner in the James Lind Alliance Pressure Ulcer Partnership, with members contributing to the prioritisation of pressure ulcer treatment and prevention uncertainties. These uncertainties are publicly available to inform future research [see www.jlapressureulcerpartnership.co.uk (accessed 20 February 2015)].

Developing materials

A website has been developed by PURSUN UK [see www.pursun.org.uk (accessed 20 February 2015)]. In addition, PURSUN UK has contributed to the international consensus document *Optimising Wellbeing in People Living with a Wound*, published by Wounds International [see www.woundsinternational.com/clinical-guidelines/international-consensus-optimising-wellbeing-in-people-living-with-a-wound (accessed 20 February 2015)].

Developing and sharing patient and public involvement methods

Developing a completely new service user network has given us the opportunity to be creative in our approach and develop innovative involvement models. These models have been shared with the UK PPI community. The PPI model used as part of the severe pressure ulcer study (see *Chapter 4*, *Patient and public involvement*) has been presented at three national conferences (INVOLVE, Involving People Wales and Tissue Viability Society) and forms part of an INVOLVE video resource on PPI in data interpretation and analysis [see www.invo.org.uk/resource-centre/conference/involve-conference-gallery/ (accessed 20 February 2015)]. A video about the Severe Pressure Ulcer PPI event was also made by PURSUN UK and has been widely disseminated online [see https://youtu.be/bgg6zkbILrg (accessed 21st July 2015)]. The novel approach of using the Patient Learning Journey as a model for service users contributing to research rather than health education has also been included as a case study in the INVOLVE training and development guidelines [see www.invo.org.uk/training-case-study-13-2/ (accessed 20 February 2015)].

Media

Working with service users has enabled us to more effectively engage with local and national media. Members of PURSUN UK have been interviewed for the *Yorkshire Evening Post* [see www.yorkshirepost.co.uk/news/at-a-glance/general-news/yorkshire-group-spearheads-bedsores-care-drive-1-3786988 (accessed 20 February 2015)] and the *Daily Mail* [see www.dailymail.co.uk/health/article-2093904/Bed-sores-How-does-local-hospital-compare.html (accessed 20 February 2015)] and we have found that journalists are more likely to run a health-related story if it has a real-life, human interest aspect to it.

Discussion

Our patient and public involvement methods

The growing role of PPI throughout the PURPOSE programme has been described. This likely reflects the situation in other research projects that need to recruit service users once the project is already under way, especially when projects span a number of years. This may be because of recruitment challenges or because it is determined that additional input from a particular group of people is needed or may be because of existing service user partners stepping down. Introducing service users to studies that are already under way can be challenging, particularly when relationships have already been formed within the project team.

Although members of PURSUN UK were not involved at the grant application stage and were therefore not part of setting the programme themes, they have found common ground with both each other and the project team. These shared goals have made collaboration possible. We recognise that early involvement is considered good practice[30] and that there are areas throughout the PURPOSE programme (particularly in the early stages of programme delivery) where additional PPI might have been useful, for example involvement in

the qualitative part of the PU-QOL study. However, the lack of a PPI infrastructure in the field made this difficult. The establishment of PURSUN UK and associated innovative approaches to PPI has addressed this need and is just one way in which PURPOSE intends to leave a legacy beyond the life of the programme.

Facilitating PPI effectively requires specialist skills. The creation of the PPI officer post brought specialist engagement expertise, dedicated time, innovative solutions, continuity and a single point of contact for service users. This enabled us to provide the individualised support that members of PURSUN UK require to be actively involved, for example briefing and debriefing meetings; information technology tuition and support; peer support opportunities; and practical support such as accessible venues and large-print documents.

The development of the PURSUN UK network has allowed us to move from ad hoc PPI activities at the start of the programme to a more strategic approach. Furthermore, we have found that members of PURSUN UK have helped to bridge the gap between research and practice, for example putting the PURPOSE findings in a NHS context and thinking about how findings can have the most impact. They have also highlighted continued gaps in the research and unanswered questions from the service user perspective, which will be taken forward in a future programme of work.

Our model involves a small number of service users in programme management and working with the wider network at key milestones throughout each study; this has worked well throughout the programme. We recognise that not all service users will feel comfortable in formal research environments such as the PURPOSE steering committee meetings. More informal meetings and workshops, which focus on the service user perspective, have proved invaluable. These meetings have highlighted key issues such as the importance of patient engagement in pressure ulcer prevention and treatment; the anxiety and stigma that can be felt as a result of a pressure ulcer; and the need to raise awareness of pressure ulcers with both patients and professionals.

To effectively engage with this group we have adopted a highly flexible and innovative methodology. We have used an asset-based approach.[31] This means building on the strengths of network members by adapting our research processes, rather than risk excluding people from traditional PPI activities. For example:

- the use of role play and video to facilitate PPI in the interpretation of data from the severe pressure ulcer study (see *Chapter 4*, *Patient and public involvement*)
- the adaptation of the Patient Learning Journey model[32] for use in a research context
- the use of a live interview model as an alternative to traditional presentations
- the addition of a service user group to the consensus methodology used in the risk assessment study (see *Chapter 5*, *Service user group participants*)
- individualised support for steering committee members, including one-to-one debriefs with the PPI officer
- the integration of service user narratives into the dissemination of the quantitative pain studies.

The value of the Pressure Ulcer Research Service User Network UK to the service users involved

The reciprocal nature of engagement has been central to the success of PPI in this programme. In addition to PPI having a positive impact on research processes and outputs, service users have also reported that it has been a positive and rewarding experience for them. People have commented on increased confidence, self-worth, knowledge of research and awareness of their own health. They have valued the peer support that PURSUN UK provides and the opportunities to enter into an equal dialogue with researchers and clinicians.

> *I've loved putting my input into the work the group are doing. I had to give up everything [because of my severe pressure ulcer] and it has given me something to do. I feel like I'm back in the world again!*
>
> *PURSUN UK member*

> *PURSUN is a safe place to learn from sharing experiences with each other, and the comfort that comes from knowing that it is a safe environment cannot be underestimated. This should be acknowledged, even if it wasn't originally on the radar of those wanting to set up a service user group*
>
> *PURSUN UK member*

The networks formed as part of their work with PURSUN UK have led to other opportunities for people, including paid positions. For example, people have become involved in teaching activities elsewhere in the University of Leeds and have joined research projects/service user groups in other topic areas.

Conclusion

This chapter outlines both the challenges and advantages of engaging with a previously seldom-heard group. A mixture of established good practice techniques and innovative PPI approaches has allowed us to move beyond the PPI plan outlined in our grant application and beyond what others have achieved in this field. Although we have worked exclusively within pressure ulcer research, the strategies outlined here could help service users and researchers work together in other contexts.

Chapter 3 Work package 1: pain

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Abstract

Introduction: Patients with pressure ulcers have reported that pain is their most distressing symptom and that pain at 'pressure areas' was experienced before the clinical manifestation of pressure ulcers but that the pain was ignored by nurses. The primary aim of the research was to determine the extent of pressure area and pressure ulcer pain and explore the role of pain as a predictor of category 2 and above pressure ulcers in acute hospital and community populations.

Methods: The pain work package comprised three research projects: (1) a nested multicentre pain prevalence study in three NHS acute hospital trusts, including all inpatients; (2) a nested pain prevalence survey in two community NHS trust localities incorporating a comparison of case-finding methods, including only patients with pressure ulcers; and (3) a multicentre prospective cohort study of pressure ulcer risk factors in acute hospital and community patients.

Results: In the hospital prevalence study a total of 3397 patients in nine acute hospitals were included in routine pressure ulcer prevalence audits and, of these, 2010 (59.2%) participated in the nested pain prevalence study. The community routine pressure ulcer prevalence audit identified 287 patients with pressure ulcers and, of these, 176 (61.3%) participated in the nested pain prevalence study. The overall prevalence of pressure ulcers was 0.58 per 1000 adult population, with differences observed between localities (locality 1 = 0.77 and locality 2 = 0.40). The unattributed pressure area-related pain prevalence was 16.3% (327/2010) in the hospital population, which included patients with and without pressure ulcers. In the hospital population with no observable pressure ulcers, 12.6% (223/1769) reported unattributed pressure area-related pain. The prevalence of unattributed pressure area-related pain in patients with pressure ulcers was 43.2% (104/241) in hospital patients and 75.6% (133/176) in the community patients. The detailed pain assessment of 160 hospital and 37 community patients identified pressure area-related pain on skin areas assessed as normal as well as all grades of pressure ulcer. The distribution of pain intensity measured using a 0–10 nominal rating scale was similar for all grades. The dominant type of pain in hospital patients was inflammatory pain (70.3% torso and 60.3% limb), whereas in the community patients neuropathic pain was dominant (54.5% torso and 61.1% limb). The cohort study of 632 acutely ill hospital and community patients identified significant evidence that the presence of pain at a skin site (assessed as normal, altered but intact or category 1) is an independent predictor for developing a category 2 or above pressure ulcer in four multivariable models: a priori logistic regression model, overdispersion logistic regression model and an accelerated failure time model for analyses conducted on a patient level and a multilevel logistic regression model for the analysis conducted on a skin-site level.

Conclusions: We have identified that a significant minority of hospital inpatients without pressure ulcers suffer pressure area-related pain, that approximately 40% of hospital patients and 75% of community patients with pressure ulcers report pain, that pain severity is not related to the severity of the ulcer and that both inflammatory and neuropathic pain are observed. Differences in pressure ulcer prevalence rates highlight the need for effective case ascertainment in the community setting. We have also established that the presence of pain (on skin areas assessed as normal, altered but intact or category 1 pressure ulcer) increases the risk of development of category 2 and above pressure ulcers and accelerates the time to their development. This is an area of practice that requires improved pain assessment; the incorporation of pain into risk assessment; preventative interventions in response to pain; and treatment strategies to alleviate pain.

Introduction

Our pre-programme grant qualitative work[33,34] and systematic review of the pressure ulcer quality-of-life literature[9] found that patients with pressure ulcers report that pain is their most distressing symptom. In addition, the work highlighted that pain at 'pressure areas' (see *Definition of terms*) was experienced by patients before the clinical manifestation of pressure ulcers but that the pain was ignored by nurses. Patients blamed nurses when a pressure ulcer developed subsequently, because of the lack of action. 'Patients felt that they were responsible for communicating pain and that their care provider was responsible for attending to it, but patients' views and concerns did not always prompt action and many healthcare professionals dismissed patients' reports of pain at pressure areas'.[9,33,35]

As part of the programme grant we carried out a mixed-methods systematic review, in which qualitative and quantitative studies of patients' reports of pressure ulcer pain were identified and synthesised[36] (see *Chapter 6*, *Pressure ulcer-related pain: systematic review*). Pain was reported as debilitating, reducing the individual's ability to participate in physical and social activities, adopt comfortable positions, move, walk and undergo rehabilitation.[36] Patients with pressure ulcer pain described their experience as 'endless pain' characterised by a constant presence, needing to keep still and equipment and treatment pain.[9,34,37] This confirmed the importance of pain as a feature of living with a pressure ulcer.

Reviews of the epidemiological literature carried out by Girouard and colleagues[38] and Pieper and colleagues[39] identified eight studies reporting the prevalence of pain associated with pressure ulcers in study populations ranging from 20 to 186 participants, in diverse settings including hospitals and community and palliative care. In the four largest studies (> 100 participants), pressure ulcer pain prevalence estimates ranged from 37% to 66%.[40–43] The reviews highlight the limitations of the existing literature, including small sample sizes, the use of non-validated measures of pain, including nurse-assessed pain outcomes, and an absence of studies that report the dominant types of pain: nociceptive pain (inflammatory) and neuropathic pain (resulting from nerve damage or tissue ischaemia).[44] "Understanding the characteristics of pain is important as successful pain management depends upon using interventions that address the cause(s) of the pain. A further problem with research in the field is that pain reports are limited to Category 2 and above PUs [pressure ulcers].[35,38,39,45] Pain associated with Category 1 PUs is not reported in most studies, nor is the presence of pain at 'pressure areas.'" Despite patient reports that pain at 'pressure areas' preceded pressure ulcer development, our risk factor systematic review[46] (see *Chapter 5*) did not identify any risk factor studies that included pain as a candidate risk factor in univariate or multivariable analysis.

'In summary, qualitative evidence identifies pain preceding PU development and in PU management [as an important issue for patients]. Previous epidemiological research has focused on patients with existing PUs and a limitation of the literature is the lack of evidence relating to the extent of pain preceding PU development, the extent of pain associated with Category 1 PUs (the most prevalent PU Category), the type of pain (i.e. inflammatory or neuropathic)'[45] and the relationship between pain at 'pressure areas' and subsequent category 2 pressure ulcer development. We therefore proposed to determine both the extent of the problem and explore the role of pain as a predictor of pressure ulcer development in acute hospital and community populations.

Research overview

Work package 1 comprised the following pain prevalence and cohort studies:

1. the prevalence of pressure area-related and pressure ulcer pain in hospitalised patients (see *Pain prevalence in the hospital population*)
2. the prevalence of pressure area-relataed and pressure ulcer pain in community patients (see *Pain prevalence in the community population*), including a substudy comparing community pressure ulcer case-finding methods (see see *Routine pressure ulcer audit: community setting*)
3. pain cohort study exploring the role of pain as a predictor of category 2 pressure ulcers in acute hospital and community populations (see *Pain and pressure ulcer risk: cohort study*)

Definition of terms

This is the first pain research undertaken in patient populations with and without pressure ulcers. To describe pain in the study populations, we developed and used the following four terms: (1) pressure area; (2) pressure area-related pain; (3) pressure ulcer pain and (4) unattributed pressure area-related pain as follows (see *Glossary* for description of terms):

- *Pressure area*. A body site where pressure ulcers commonly develop; most commonly these include the sacrum, buttocks, ischial tuberosities, hips, heels, ankles and elbows.
- *Pressure area-related pain*. Defined as pain, soreness or discomfort on any pressure area.
- *Pressure ulcer pain*. Defined as pain, soreness or discomfort on a body site with an observable pressure ulcer of category 1 or above.
- *Unattributed pressure area-related pain*. Defined as pain, soreness or discomfort reported by patients on a pressure area/pressure ulcer but in which the body site is not specified/recorded.[35]

Pain prevalence in hospital and community populations

To assess the extent of pressure area-related and pressure ulcer pain we undertook two cross-sectional studies in three acute and two community NHS trusts to estimate prevalence. In the hospital setting we were able to nest the pain prevalence study into routine annual pressure ulcer audit methods and pain was assessed for all patients able to respond to pain screening questions, including those with and those without pressure ulcers. Our original plan (see the protocol in *Appendix 3*) assumed that community prevalence methodology was similar to long-standing and well-established acute hospital methods, with nurses undertaking a comprehensive skin assessment of each patient.[47] However, the two participating community trusts had developed different case-finding methods[48] and this, together with the scale of the data collection task in the community setting, led to an adaptation of the original plan and limited the pain prevalence estimates to the patient population with pressure ulcers, which is reflected in the objectives.

Objectives

Pain prevalence in the hospital population

Objectives were to:

i. estimate the unattributed pressure area-related pain prevalence in a hospital population of patients with and without pressure ulcers
ii. estimate the pressure area-related pain prevalence in patients with no observable pressure ulcers
iii. estimate the pressure ulcer pain prevalence in patients with pressure ulcers
iv. describe the intensity and type of pressure area-related and pressure ulcer pain in a hospital population of patients with and without pressure ulcers
v. explore the association between pain intensity, type of pain and pressure ulcer classification in a hospital population of patients with and without pressure ulcers.

Pain prevalence in the community population

Objectives were to:

i. estimate the prevalence of unattributed pressure area-related pain within a community population of patients with pressure ulcers
ii. assess the intensity and type of pressure area-related and pressure ulcer pain within a community population of patients with pressure ulcers
iii. describe the intensity and type of pressure area-related and pressure ulcer pain within a community population of patients with pressure ulcers
iv. explore the association between pain intensity, type of pain and pressure ulcer classification within a community population of patients with pressure ulcers
v. compare and contrast community pressure ulcer prevalence case-finding methods.

Methods

Study design

We undertook nested, multicentre, cross-sectional studies in three acute hospital NHS trusts[35] and two large community trusts in England[45] embedding the pain prevalence study into routine pressure ulcer audits. To identify patients who had unattributed pressure area-related pain, questions about pain were added to the routine annual pressure ulcer prevalence audits undertaken in the participating NHS trusts. To estimate the prevalence of pressure area-related and pressure ulcer pain and to explore the association between pain and pressure ulcer classification, patients who reported pain were invited and consented to undergo a full pain assessment (see *Appendix 5* for the consent form).

Nesting the pain prevalence study within routine pressure ulcer prevalence audits meant that we collected data for the total eligible patient population in each setting. The routine NHS audits collect unlinked anonymous data and patient consent is not required to ensure that accurate pressure ulcer prevalence data are obtained for the total eligible population. Nesting the study within routine pressure ulcer prevalence audits, however, limited the number of data items that could be collected. Furthermore, in the community the two trusts defined their denominator population differently and adopted different pressure ulcer case-finding methods.[48]

Setting

Three acute NHS hospital trusts took part. One trust included three district general hospitals. The other two NHS trusts were large teaching hospitals and together included four main and two satellite hospitals. This meant that the patient population consisted of those in general secondary care and regional/supraregional specialist services from a total of nine hospitals.

The community NHS trusts consisted of locality 1, serving an urban population of 292,179, and locality 2, serving a rural population of 311,991.[49]

Each NHS community trust provides general and tissue viability specialist nursing care to patients residing in their own homes and residential homes as well as community/rehabilitation/hospice inpatient facilities. In addition, each trust provides tissue viability specialist nursing care to patients residing in nursing home settings.

Routine pressure ulcer audit: hospital setting

Eligibility

The population included 'all inpatients of 18 years of age or older who were in hospital on the date of the participating Trusts' PU prevalence audit. Patients in paediatric, obstetric and psychiatric care settings were excluded from the study as the prevalence of PU in these settings is very low, and hence the data collection to information burden ratio is unacceptably high in these settings.'[50]

Patient identification method

Routine pressure ulcer prevalence audits in the participating acute trusts included training of a responsible nurse for each ward, completion of an audit form for each inpatient at 06.00 on the audit day, cross-referencing of the number of occupied beds on each ward and the number of audit forms submitted by an audit team and verification of data by an audit team comprising the tissue viability team and members of the mattress suppliers of the participating NHS trusts (as part of their mattress supply contract). The date of the prevalence audit for each hospital was determined locally.

Routine pressure ulcer audit: community setting

Eligibility

The target population was all patients aged ≥ 18 years who were identified as having a pressure ulcer. Patients in paediatric, obstetric and psychiatric community care settings were excluded.

Patient identification method

A number of challenges are faced when determining 'community prevalence': (1) defining the time period for data collection, (2) defining the term 'community' for case ascertainment to estimate the numerator and (3) defining the denominator population. 'In the UK, within each locality there are six key healthcare providers in the community including community nursing services, residential homes, rehabilitation units, specialist palliative care units, nursing homes and General Practitioners. NHS community trusts provide general and specialist community nursing services to patients residing at home and also tissue viability specialist nursing to high risk patients and those with complex wounds residing in independent sector residential and nursing home facilities. Residential home facilities provide only social care and therefore a patient in this setting with a pressure ulcer would be referred to the community nursing service. Rehabilitation units, specialist palliative care units and nursing home facilities include 'nursing care' and only complex patients are referred to the community nursing service. General Practitioners usually refer patients with a pressure ulcer to community nursing services. To establish true community prevalence would require named patient data from each health-care provider. However, this is not achievable without considerable resource'[48] and the data burden and use of named patient data in routine audits is not considered justified for the gain in precision of prevalence estimates.

Both localities completed data collection over a 6- to 8-week period. 'The two localities applied different methods for case finding as per their local pressure ulcer audit practice.'[48] Locality 1 requested that community nurses assess all of the patients on their community nursing caseload and that a nominated nurse in each residential home, specialist palliative care unit, rehabilitation unit and nursing home in the locality assess all inpatients/residents to identify patients with pressure ulcers.[47] An audit form was completed for each patient (i.e. those with and those without pressure ulcers). Locality 2 identified patients with known pressure ulcers from the community nursing caseload records and the community nurses completed an audit form only for those patients identified as having a pressure ulcer[48] [note that patients treated by a general practitioner only (i.e. not also under the care of a general or specialist community nursing service) were not identified in the case-finding method by either locality 1 or locality 2]. In both trusts each patient identified through case finding as having a pressure ulcer had a tissue viability team member visit to verify the skin assessment recorded by the community nurse.

Pain prevalence eligibility criteria

Pain prevalence inclusion criteria

In addition to the standard pressure ulcer audit data, the ward/community nurses were asked to consider whether each patient was able to report the presence or absence of pain. Patients who were considered able to report pain were eligible for inclusion in the pain prevalence study and were asked two screening questions (see following section on assessments) relating to pressure area-related pain by a member of the tissue viability team.

Pain prevalence exclusion criteria

Patients were excluded from the pain prevalence study when it was considered ethically or clinically inappropriate by the ward nurse/clinical team, for example very sick patients or those for whom death was considered to be imminent. When patients were assessed as not able to report pain, this was recorded along with the reason for ineligibility.

Detailed pain assessment inclusion criteria and consent

Patients in the hospital and community settings who answered 'yes' to both pain screening questions were provided with a verbal explanation of the detailed pain assessment component of the study and a written information leaflet (see *Appendix 4*) by the tissue viability team member and were then invited to take part in a full pain assessment. Consenting patients underwent a detailed pain and skin assessment (see *Detailed pain assessment*).

Assessments

Unlinked anonymised individual patient audit data were recorded by a designated ward or community nurse trained in the use of the data collection form and skin assessment as part of the preparation for the audit. Data recorded included place of assessment (hospital/community and ward specialty, patient's own home, nursing home, residential home, hospice, community bed), date of birth, gender, height, weight, ethnicity, mobility and risk assessment scale total score (using either the Waterlow score[50] or the Braden scale[51] as per local policy). Skin was assessed using the 1998 EPUAP[24] classification and recorded for a minimum of 13 skin sites (sacrum, left and right buttocks, ischial tuberosities, hips, heels, elbows and ankles). The 1998 EPUAP classification (and not the revised EPUAP/NPUAP 2009 version)[1] was used as this was the version in routine use at the participating centres/localities. In addition, the presence of an unstageable pressure ulcer, other type of wound or normal skin were confirmed or skin status was recorded as not applicable (e.g. amputation) or unable to assess.

When patients were assessed as not able to report pain this was recorded along with the reasons for ineligibility. When ward/community staff indicated that the patient was well and able to report pain, a member of the tissue viability team asked the patient two pain screening questions as follows:[35,45]

1. At any time, do you get pain, soreness or discomfort at a pressure area (prompt: back, bottom, heels, elbows or other as appropriate to the patient)? (Yes or no)
2. Do you think this is related to either your pressure ulcer OR lying in bed for a long time OR sitting for a long time? (Yes or no)

These questions were adapted from the case screening questions used in a large postal survey of pain prevalence in the UK.[35,52] Unlinked anonymous individual patient data were recorded for both questions. The site of the pain, soreness or discomfort was not recorded (i.e. the pressure area/pressure ulcer pain was unattributable to individual body sites).

Detailed pain assessment

Patients who answered 'yes' to both pain screening questions and who consented to further assessment underwent a detailed pain and skin assessment by a member of the tissue viability team that included pain intensity, type of pain and skin status/grade of ulcer (as above) on a minimum of 13 skin sites (as above). The patient risk profile was assessed using the Braden scale subscales to allow description of the patient population and comparison with the wider literature.

'Pain was assessed by asking patients to report the pain intensity (for most severe pain over the past week) for all pressure area sites using a numerical rating scale of 0–10.'[45,53,54] Patients were also asked to identify their 'most painful torso and limb skin sites and these were assessed using the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) Pain Scale.[55] The LANSS Scale is a clinically validated tool which allows assessment of neuropathic and inflammatory pain [and has been used in a wide variety of clinical settings[55]]. It consists of a brief assessment and is easy to score in the clinical setting. The questionnaire contains 5 symptom items and 2 clinical sensory testing items associated with neuropathic pain.'[45] The responses to each of the seven items are scored and summed to provide a total score. If the LANSS total score is < 12, neuropathic mechanisms are unlikely and the pain is classified as inflammatory pain. If the LANSS total score is ≥ 12, neuropathic mechanisms are likely to be contributing to the pain and it is classified as neuropathic.

Staff training and preparation

Ward and community nurses were trained locally as per local trust standard pressure ulcer audit practice. Members of the tissue viability team were trained in study procedures, including pain assessment and skin assessments, by the programme manager (LW). No formal inter-rater reliability assessment was undertaken as previous research has demonstrated high agreement between specialist nurses and clinical research nurses in skin assessment and pressure ulcer classification.[56]

Data processing

All data returned to the Clinical Trials Research Unit (CTRU) for data processing were anonymous. Data were entered into a bespoke MACRO (version 3; MACRO, Infermed, London, UK) database and range and consistency data checks were carried out to assess the accuracy of the data.

Sample size

For the priori sample size we planned to use a minimum of two acute NHS trusts with an estimated patient population of 2000 and two community NHS trusts with an estimated community nursing caseload of 6000 community patients; therefore, it was planned to include approximately 8000 patients in the prevalence audit.

The a priori sample size was based on the following assumptions:

- the prevalence of pressure ulcers in hospital patients is 10% and in community patients is 5%[2]
- 30% of patients have pressure ulcers of grades 2–4/unstageable ulcers, of whom 25–50% would report pressure-area related pain[40–43]
- 70% of patients have pressure ulcers of grade 1, of whom 10–30% would report pressure area-related pain
- 90% of hospital and 95% of community patients have no pressure ulcers
- 2.5–5% of patients without pressure ulcers would report pressure area-related pain.

Based on these assumptions we estimated that between 259 and 555 patients would report pressure area-related pain (i.e. that 3–7% of patients would report pressure area-related pain; *Table 2*). A sample of 8000 patients would enable us to estimate a pressure area-related pain prevalence of 3% to within ±0.38% ($n = 7742$) and a pressure area-related pain prevalence of 7% to within ±0.56% ($n = 7975$).

Analysis

Analysis included data summaries and no inferential statistical testing was planned or undertaken. The denominator for the acute hospital pressure ulcer prevalence was the total inpatient population. The community pressure ulcer prevalence was calculated per 1000 of the estimated total population of adults aged ≥ 18 years for each site (240,038 locality 1 population aged ≥ 18 years; 251,891 locality 2 population aged ≥ 18 years).[49]

TABLE 2 Pain prevalence: estimated number of patients with pressure area-related pain

			Pressure area-related pain	
Setting	Pressure ulcer status		*n*	%
Hospital ($n = 2000$)	No PU (90%; $n = 1800$)		45–90	2.5–5
	PU (10%; $n = 200$)	Category 1 (70%; $n = 140$)	14–42	10–30
		Categories 2–4 (30%; $n = 60$)	15–30	25–50
Community ($n = 6000$)	No PU (95%; $n = 5700$)		142–285	2.5–5
	PU (5%; $n = 300$)	Category 1 (70%; $n = 210$)	21–63	10–30
		Categories 2–4 (30%; $n = 90$)	22–45	25–50

PU, pressure ulcer.

'Percentages were calculated using the total number of patients from the relevant population as the denominator (i.e. including all patients with missing data for that variable).'[45] When another skin condition or chronic wound was indicated, the specific skin site was excluded from the analysis. 'All analyses were carried out using SAS software [version 9.2; SAS Institute Inc., Cary, NC, USA]. All percentages were rounded to 1 decimal place. Means, medians, standard deviations [SDs] and ranges were summarised to one more decimal place than the data collected.'[45]

Type of pain was determined using the results of the seven-item LANSS scale,[5] with the responses to each of the seven items scored and summed to provide a total score. Pain was classified as inflammatory pain when the LANSS total score was < 12 and neuropathic pain if the LANSS total score was ≥ 12.

Ethical approval

The studies were approved by the Leeds Central Research Ethics Committee prior to data collection (reference number 09/H1313/14).

Results

Pressure ulcer prevalence: hospital population

Data collection was undertaken between 15 September 2009 and 3 March 2010. From across nine acute hospitals, a total of 3397 patients (see *Appendix 1*) were included in the routine pressure ulcer prevalence surveys and this is our target hospital population.[50] *Figure 2* details the flow of patients through each stage of the process. The number of patients audited by specialty is presented in *Table 3*.

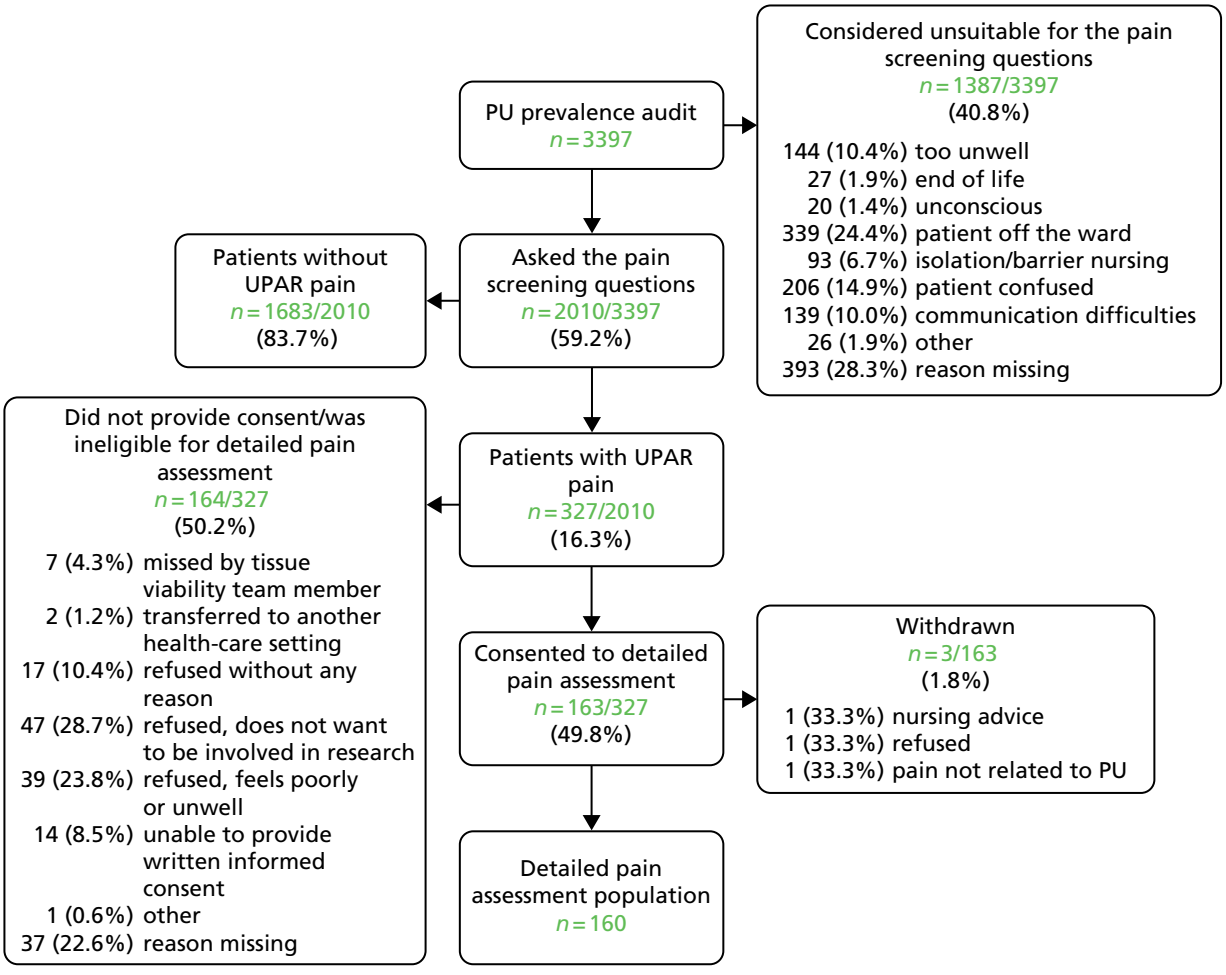

FIGURE 2 Participant flow: hospital population. PU, pressure ulcer; UPAR, unattributed pressure area-related.

TABLE 3 Pressure ulcer prevalence hospital population by specialty

Specialty	Numbers of participants	%
Medicine	1348	39.7
Surgery	868	25.6
Elderly medicine	380	11.2
Orthopaedic and trauma	305	9.0
Oncology	211	6.2
Critical care	179	5.3
Rehabilitation	79	2.3
Burns	15	0.4
Clinical decision units	8	0.2
Missing	4	0.1
Total	3397	100

The median age of patients was 70 years [mean 65.8 (SD 19.23), range 18–103 years]. The numbers of men and women were similar (48.7% male; 1655/3397) and 7.2% (243/3397) were non-Caucasian.[35] In total, 53.9% of patients (1830/3397) were assessed using the Waterlow scale and of these 1062 (58.0%) were classified as 'at risk' (score of ≥ 10); 46.1% of patients (1567/3397) were assessed using the Braden scale and of these 532 (34.0%) were classified as 'at risk' (score of ≤ 18) (*Table 4*).

Of the 3397 patients included, 502 (14.8%) were reported to have 1066 pressure ulcers [median 1.0, mean 2.1 (SD 1.63), range 1–13 per patient]. The majority (70.5%; 752/1066) of reported pressure ulcers were grade 1, approximately one-fifth were grade 2 (22.2%; 237/1066) and a small percentage (7.2%; 77/1066) were grades 3–4/unstageable.[35]

Pain prevalence: hospital population

Of the 3397 hospital patients in the pressure ulcer audit sample, 2010 (59.2%) were considered well enough to respond to the pain questions and hence were eligible for the pain prevalence study (see *Figure 2*).

The pain prevalence population demographics were similar to those of the total hospital prevalence population (see *Table 4*). The median age of patients was 68 years [mean 64.8 (SD 18.57), range 18–100 years], almost half (980/2010; 48.8%) were male and 122 (6.1%) were non-Caucasian. In total, 49.6% (997/2010) were assessed using the Waterlow scale and of these 504 (50.6%) were classified as 'at risk' (score of ≥ 10); 50.4% (1013/2010) were assessed using the Braden scale and of these 263 (26.0%) were classified as 'at risk' (score of ≤ 18).

A total of 241 patients (12.0%) were reported to have 491 pressure ulcers [median 1.0, mean 2.0 (SD 1.44), range 1–9 per patient]. As shown in *Table 4*, there were similar grades of pressure ulcers in both the total hospital prevalence population and the pain prevalence population. The majority (357/491; 72.7%) of reported pressure ulcers in the pain prevalence population were grade 1, 20.4% (100/491) were grade 2 and 6.9% (34/491) were grades 3–4/unstageable.

TABLE 4 Demographics for the total, pain and detailed pain assessment hospital populations

Characteristic	Total hospital prevalence population	Pain prevalence population	Detailed pain assessment population
Total population, *n*	3397	2010	160
Age (years)			
Median	70.0	68.0	69.0
Mean (SD)	65.8 (19.23)	64.8 (18.57)	66.2 (18.23)
Range	18.0–103.0	18.0–100.0	18.0–99.0
Male, *n* (%)	1655 (48.7)	980 (48.8)	80 (50.0)
'At risk', *n/N* (%)			
Waterlow	1062/1830 (58.0)	504/997 (50.6)	
Braden	532/1567 (34.0)	263/1013 (26.0)	114/160 (71.3)
Ethnicity, *n* (%)			
White	2963 (87.2)	1774 (88.3)	154 (96.3)
Other	243 (7.2)	118 (5.9)	4 (2.5)
Missing	191 (5.6)	118 (5.9)	2 (1.3)
Patients with PUs, *n* (%)	502 (14.8)	241 (12.0)	75 (46.9)
Total number of PUs	1066	491	139
Number of PUs per patient			
Median	1.0	1.0	1.0
Mean (SD)	2.1 (1.63)	2.0 (1.44)	1.9 (1.23)
Range	1.0–13.0	1.0–9.0	1.0–5.0
Grade of PUs reported, *n* (%)			
Grade 1	752 (70.5)	357 (72.7)	97 (69.8)
Grade 2	237 (22.2)	100 (20.4)	32 (23.0)
Grade 3	45 (4.2)	18 (3.7)	4 (2.9)
Grade 4	18 (1.7)	10 (2.0)	3 (2.2)
Unstageable	14 (1.3)	6 (1.2)	3 (2.2)

PU, pressure ulcer.

'Of the 2010 people asked the pain questions, 327 said yes to both questions, indicating they had pain on one or more skin sites with or without a PU, providing an overall UPAR [unattributed pressure area-related] pain prevalence of 16.3%' (see *Figure 2*). In total, 1769 patients did not have any pressure ulcers and 223 of these patients 'reported pain, an UPAR pain prevalence of 12.6%. Of the 241 people with PUs, 104 patients reported pain at one or more PU site, an UPAR pain prevalence of 43.2%.'[35]

Detailed pain assessment: hospital population

Of the 327 who answered 'yes' to both pain screening questions, 164 (50.2%) were not able, or declined, to participate in the full pain assessment and 163 (49.8%) consented. Three patients were subsequently withdrawn and therefore the analysis population of eligible patients with unattributed pressure area-related pain who participated in the detailed pain assessment was 160 (*Figure 3*).

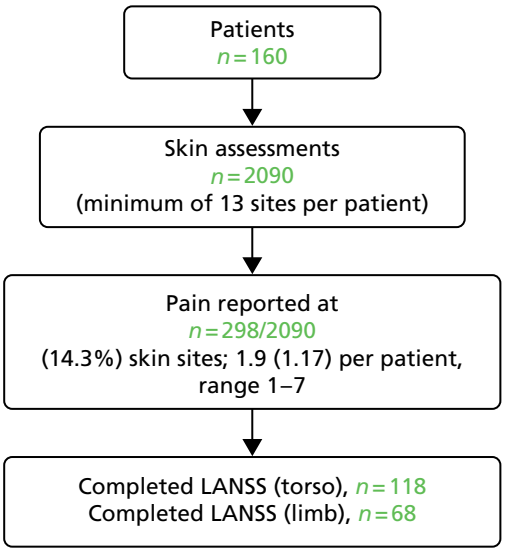

FIGURE 3 Participant flow: detailed pain and skin assessments: hospital population.

The median age of these 160 patients was 69.0 years [mean 66.2 (SD 18.23), range 18–99 years] and half (80/160; 50.0%) were men. Almost three-quarters (114/160; 71.3%) of patients with unattributed pressure area-related pain were assessed as 'at risk' on the Braden scale and four (2.5%) were non-Caucasian. A total of 75 (46.9%) patients were reported to have 139 pressure ulcers [median 1.0, mean 1.9 (SD 1.23), range 1–5 per patient] (see *Table 4*).

A total of 2090 skin sites were assessed (see *Figure 3*), with 1933 skin sites assessed as normal, 139 assessed as pressure ulcers and skin status was not able to be assessed for 18 sites. The majority (69.8%) of reported pressure ulcers were grade 1, 23.0% (32/139) were grade 2 and 7.2% (10/139) were grades 3–4/unstageable (see *Table 4*).

Pain was reported by 157 patients on 298 skin sites (mean 1.9, SD 1.17, range 1–7 per patient). This included pressure area-related pain reported on 9.8% (190/1933) of skin sites assessed as 'normal' and pressure ulcer pain for 68.0% (66/97) of grade 1 pressure ulcers, 84.4% (27/32) of grade 2 pressure ulcers and 90.0% (9/10) of grades 3–4/unstageable ulcers (*Table 5*). The worst pain intensity reported by each patient ranged from 1 to 10, with a mean of 5.4 (SD 2.30) and median of 5.0.

TABLE 5 Detailed pain assessment: number of times pain reported by skin classification: hospital population

Skin classification	Yes, *n* (%)	No, *n* (%)	Missing, *n* (%)	Total, *n* (%)
Normal skin	190 (9.8)	1730 (89.5)	13 (0.7)	1933 (100.0)
Grade 1	66 (68.0)	30 (30.9)	1 (1.0)	97 (100.0)
Grade 2	27 (84.4)	5 (15.6)	0 (0.0)	32 (100.0)
Grade 3	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
Grade 4	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
Unstageable	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
Unable to assess	2 (22.2)	1 (11.1)	6 (66.7)	9 (100.0)
Classification missing	4 (44.4)	5 (55.6)	0 (0.0)	9 (100.0)
Total	298 (14.3)	1772 (84.8)	20 (1.0)	2090 (100.0)

Note: 160 patients completed the detailed pain assessment. Each patient had 13 skin assessments and there were 10 'other' sites assessed. The overall total therefore corresponds to $(160 \times 13) + 10 = 2090$ skin assessments.

The distribution of pain intensity is similar for each grade of pressure ulcer (*Figure 4*). In total, 128 patients identified one skin site for LANSS assessment (89 torso and 39 limb skin sites) and 29 patients identified both a torso and a limb skin site for LANSS assessment, providing 118 torso and 68 limb LANSS assessments. Nociceptive pain was dominant in both torso and limb skin sites, with 70.3% (83/118) of painful torso skin sites and 60.3% (41/68) of painful limb skin sites scoring < 12 on the LANSS assessment (*Table 6*). Neuropathic pain was observed on skin assessed as normal as well as for all grades of pressure ulcer (see *Table 6*).

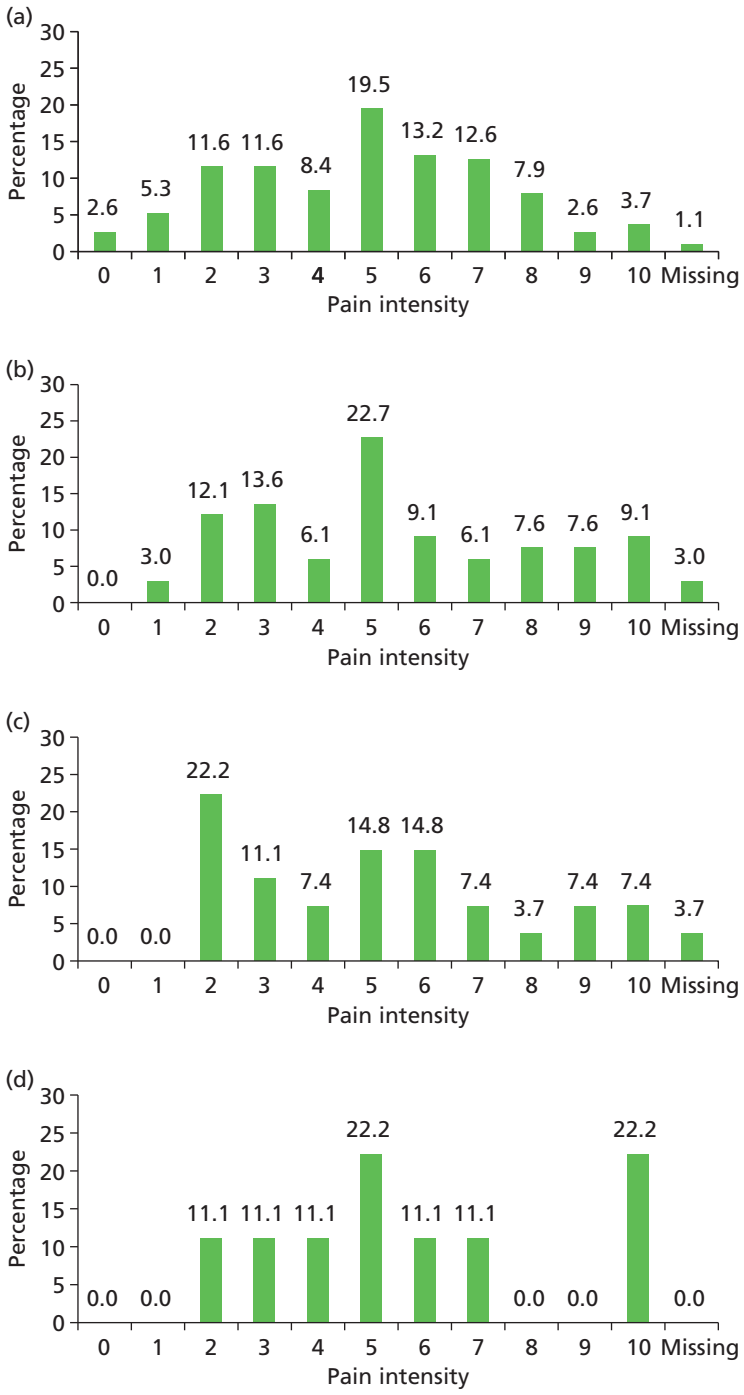

FIGURE 4 Pain intensity by skin classification: hospital population. (a) Normal skin; (b) grade 1 pressure ulcers; (c) grade 2 pressure ulcers; and (d) grades 3–4/unstageable pressure ulcers.

TABLE 6 Type of pain by skin classification for the most painful torso and limb areas: hospital population

Location	Skin classification	Nociceptive, *n* (%)	Neuropathic, *n* (%)	Missing, *n* (%)	Total, *n* (%)
Torso	Normal skin	56 (76.7)	17 (23.3)	0 (0.0)	73 (100.0)
	Grade 1	12 (54.5)	8 (36.4)	2 (9.1)	22 (100.0)
	Grade 2	12 (70.6)	5 (29.4)	0 (0.0)	17 (100.0)
	Grade 3	2 (66.7)	1 (33.3)	0 (0.0)	3 (100.0)
	Grade 4	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Unstageable	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Missing	0 (0.0)	1 (50.0)	1 (50.0)	2 (100.0)
	Total[a]	83 (70.3)	32 (27.1)	3 (2.5)	118 (100.0)
Limb	Normal skin	27 (61.4)	16 (36.4)	1 (2.3)	44 (100.0)
	Grade 1	11 (73.3)	3 (20.0)	1 (6.7)	15 (100.0)
	Grade 2	1 (20.0)	4 (80.0)	0 (0.0)	5 (100.0)
	Grade 3	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	Grade 4	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Unstageable	1 (100.0)	0 (0.0)	0 (0.0)	1 (100.0)
	Missing	0 (0.0)	0 (0.0)	1 (100.0)	1 (100.0)
	Total[b]	41 (60.3)	24 (35.3)	3 (4.4)	68 (100.0)

a The denominator here is the number of patients who completed the LANSS assessment for a torso skin.
b The denominator here is the number of patients who completed the LANSS assessment for a limb skin site.

Pressure ulcer prevalence: community population

Locality 1 collected data between 8 February and 2 April 2010 and locality 2 collected data between 12 April and 7 May 2010. *Figure 5* shows the patient flow through the stages of the process.[45]

'The two community NHS Trusts identified 287 patients with Grade 1–4/Unstageable pressure damage. The case finding methods resulted in differing prevalence rates. In locality 1, 1680 patients were assessed, and of these 185 patients were assessed as having a pressure ulcer ≥ Grade 1, a prevalence rate of 0.77 per 1000 [(185/240,038) × 1000 adults]. In locality 2, 102 patients were identified from the community nursing caseloads and assessed as having a Grade ≥ 1 pressure ulcer, a prevalence rate of 0.40 per 1000 [(102/251,891) × 1000 adults]'[45]. A notable difference between the two sites, and one that could also contribute to the difference in reported prevalence, was the patients' place of residence. In locality 1, 93 out of 185 (50.3%) patients were resident in a nursing home, whereas in locality 2 only five out of 103 (4.9%) patients were resident in a nursing home.

The median age of patients with pressure ulcers was 81 years (mean 77.8, SD 13.44, range 23–106 years), just over one-third of patients were male (100/287; 34.8%),[45] 89.6% (251/280) were assessed as being 'at risk' using either the Waterlow scale or the Braden scale and only 1.4% (4/287) were non-Caucasian (*Table 7*).

The 287 patients with pressure ulcers were reported to have 440 ulcers [median 1, mean 1.5 (SD 0.83), range 1–5 per patient]. About one-third of pressure ulcers (155/440; 35.2%) were grade 1, 40.2% (177/440) were grade 2 and 24.5% (108/440) were grades 3–4/unstageable.[45]

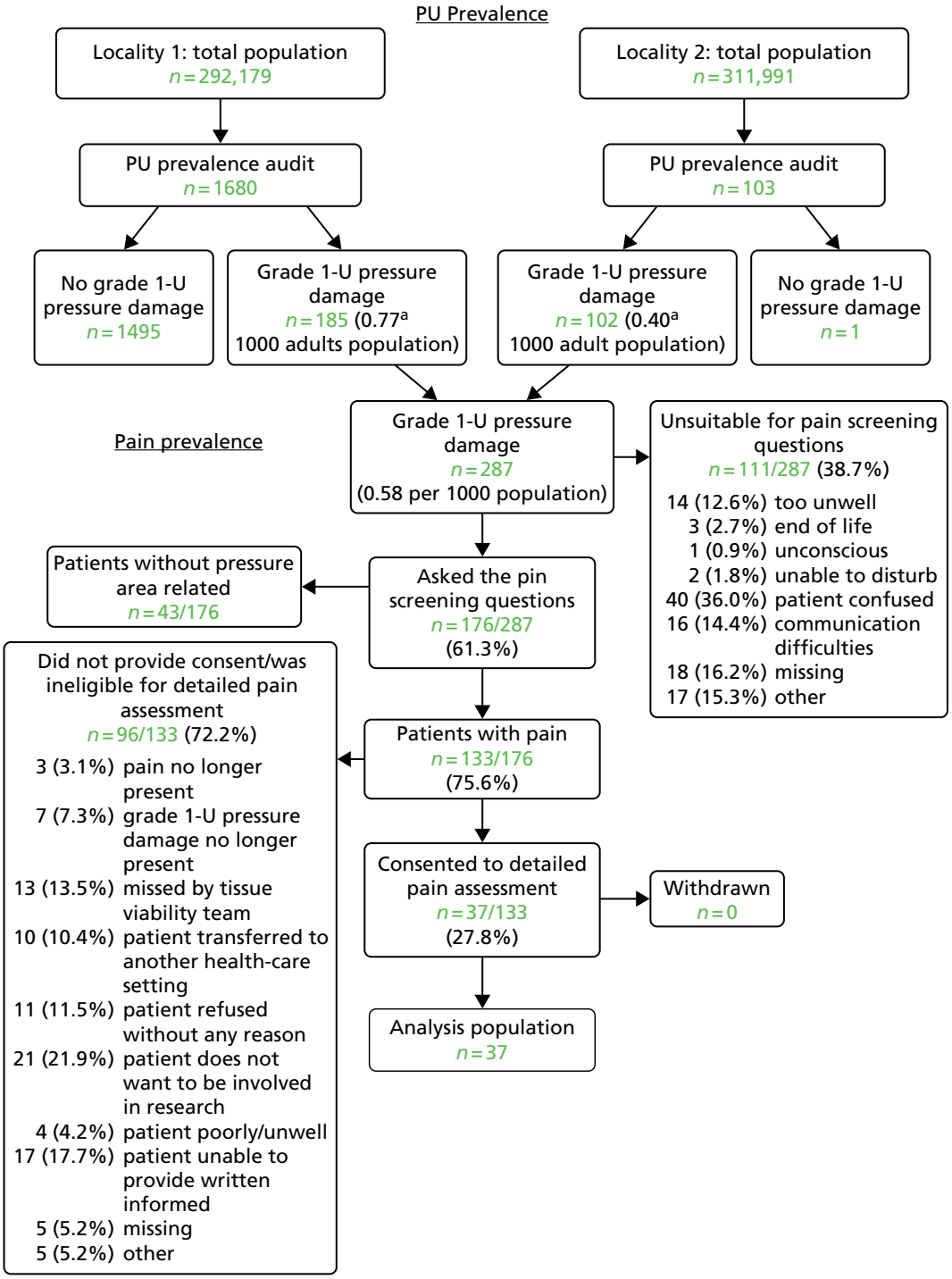

FIGURE 5 Participant flow: community population. Grade 1-U, grade 1 or above. a, Locality 1 audited all patients on the caseload whereas locality 2 audited all patients with existing pressure damage. Adapted from McGinnis *et al.*[45] © 2014 McGinnis *et al.*; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited.[45]

TABLE 7 Demographics for the total, pain and detailed pain assessment community populations

Characteristic	Total community prevalence population	Pain prevalence population	Detailed pain assessment population
Total population, *n*	287	176	37
Age (years)			
Median	81.0	79.0	75.0
Mean (SD)	77.8 (13.44)	76.2 (13.27)	72.6 (15.31)
Range	23.0–106.0	23.0–99.0	23.0–98.0
Male, *n* (%)	100 (34.8)	71 (40.3)	9 (24.3)
'At risk', *n/N* (%)			
Waterlow	38/38 (100)	16/16 (100)	
Braden	213/242 (88.0)	132/156 (84.6)	25/37 (67.6)
Ethnicity			
White	272 (94.8)	171 (97.2)	37 (100.0)
Other	4 (1.4)	2 (1.1)	0 (0.0)
Missing	11 (3.8)	3 (1.7)	0 (0.0)
Place of assessment, *n* (%)			
Own home	134 (46.7)	108 (61.4)	26 (70.3)
Nursing home	98 (34.1)	44 (25.0)	6 (16.2)
Residential home	36 (12.5)	10 (5.7)	3 (8.1)
Rehabilitation unit	12 (4.2)	9 (5.1)	1 (2.7)
Specialist palliative care unit	5 (1.7)	4 (2.3)	1 (2.7)
Missing	2 (0.7)	1 (0.6)	0 (0.0)
Total number of PUs	440	285	54
Number of PUs per patient			
Median	1.0	1.0	1.0
Mean (SD)	1.5 (0.83)	1.6 (0.88)	1.5 (0.65)
Range	1.0–5.0	1.0–5.0	1.0–3.0
Grade of PUs reported, *n* (%)			
Grade 1	155 (35.2)	87 (30.5)	20 (37.0)
Grade 2	177 (40.2)	118 (41.4)	17 (31.5)
Grade 3	63 (14.3)	45 (15.8)	8 (14.8)
Grade 4	32 (7.3)	25 (8.8)	5 (9.3)
Unstageable	13 (3.0)	10 (3.5)	4 (7.4)

PU, pressure ulcer.

Pain prevalence: community population

Of the 287 patients with pressure ulcers, 176 (61.3%) were asked the pain screening questions. The median age of patients with pressure ulcers was 79.0 years (mean 76.2, SD 13.27, range 23–99 years), 40.3% were male (71/176), 86.0% (148/172) were assessed as being 'at risk' using either the Waterlow scale or the Braden scale and only 1.1% (2/176) were non-Caucasian (see *Table 7*).

The 176 patients with pressure ulcers were reported to have 285 pressure ulcers [median 1, mean 1.6 (SD 0.88), range 1–5 per patient]. Under one-third of pressure ulcers (87/285; 30.5%) were grade 1, 41.4% (118/285) were grade 2 and 28.1% (80/285) were grades 3–4/unstageable. The prevalence of unattributed pressure area-related pain in the community patient population who had existing pressure ulcers was 75.6% (133/176) (see *Figure 5*).

Detailed pain assessment: community population

'Of the 133 patients with unattributed pressure area-related pain, 96 were not able or declined to participate in the full pain assessment [see *Figure 5*]. Therefore, the analysis population of eligible patients who consented to the detailed pain assessment was 27.8% (37/133) of the population reporting pain.'[45]

The median age of these 37 patients was 75.0 years (mean 72.6, SD 15.31, range 23–98 years). Most (70.3%) patients were assessed in their own home, with the remainder assessed in residential or nursing homes, rehabilitation units or palliative care units. Nine patients (24.3%) were male and all were white (see *Table 7*).[45]

'A total of 481 skin sites were assessed [*Figure 6*], including 427 skin sites assessed as normal and 54 PUs (mean 1.5 per patient, SD 0.65, range 1–3). Approximately a third of PUs were Grade 1 (37.0%; $n = 20/54$), Grade 2 (31.5%; $n = 17/54$) and Grade 3–4/U (31.5%; $n = 17/54$) [see *Table 7*], with 29 (53.7%) located on a torso skin site and 25 (46.3%) located on a limb skin site.'[45]

The 37 patients reported pain on 53 out of 481 (11.0%) skin sites [median 1.0, mean 1.4 (SD 0.65), range 1–3 per patient]. 'No pressure area related pain was reported on normal skin whilst patients reported PU pain for 98.1% ($n = 53/54$) of all PUs [*Table 8*]. Pain intensity ranged from 1–10, with a mean of 6.4 (SD 2.53) and median of 7.0. There is a slightly skewed distribution of pain intensity with very similar pain levels for each grade of PU [*Figure 7*]. Thirty-one patients identified one skin site for LANSS assessment ($n = 19$ torso and $n = 15$ limb) and six patients identified both a torso and a limb skin site for LANSS assessment providing a total of 22 torso and 18 limb LANSS assessments. Neuropathic pain was slightly dominant in both torso and limb skin sites, with 54.5% ($n = 12/22$) of torso PUs and 61.1% ($n = 11/18$) of limb PUs scoring ≥ 12 on the LANSS assessment' (*Table 9*).

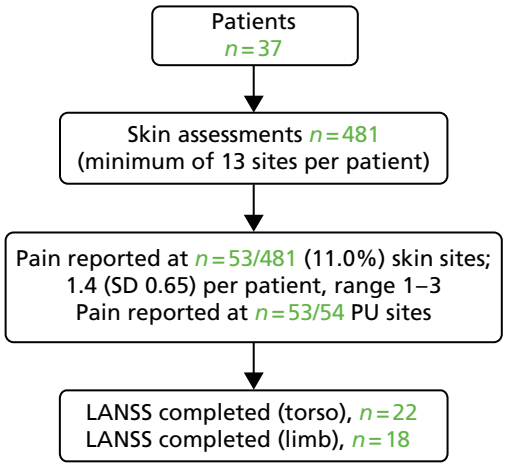

FIGURE 6 Participant flow: detailed pain and skin assessments: community population. PU, pressure ulcer. Reproduced from McGinnis *et al.*[45] © 2014 McGinnis *et al.*; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited.

TABLE 8 Detailed pain assessment: number of times pain reported by skin classification: community population

	Yes, *n* (%)	No, *n* (%)	Total, *n* (%)
Normal skin	0 (0.0)	427 (100.0)	427(100.0)
Grade 1	19 (95.0)	1 (5.0)	20 (100.0)
Grade 2	17 (100.0)	0 (0.0)	17 (100.0)
Grade 3	8 (100.0)	0 (0.0)	8 (100.0)
Grade 4	5 (100.0)	0 (0.0)	5 (100.0)
Unstageable	4 (100.0)	0 (0.0)	4 (100.0)
Total	53 (11.0)	428 (89.0)	481 (100.0)

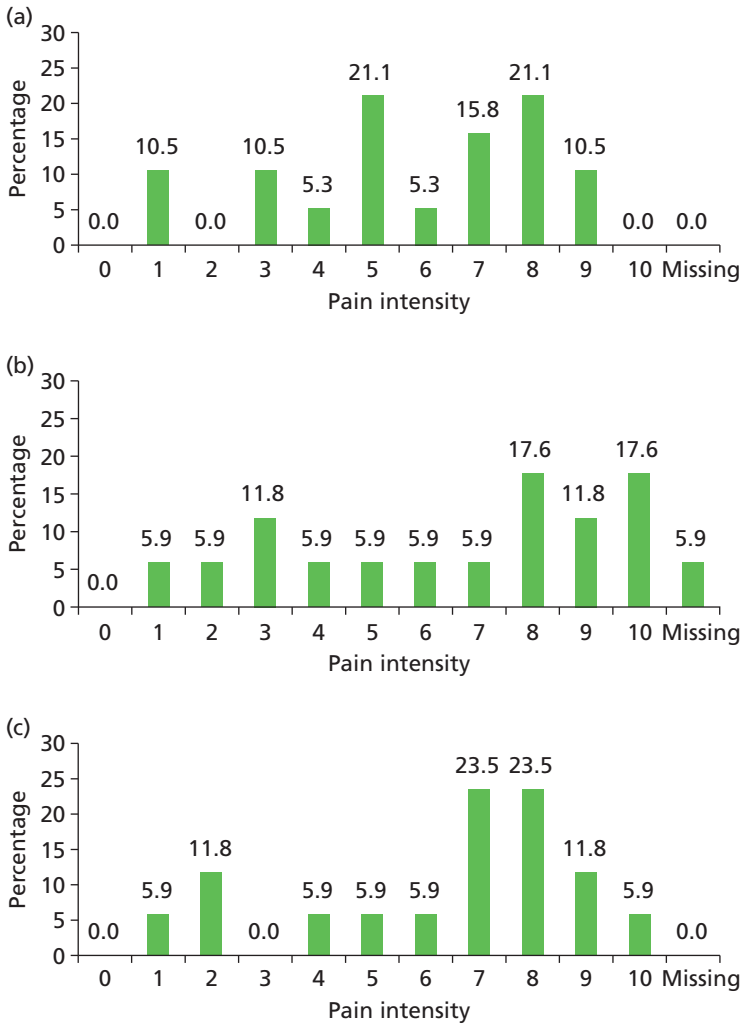

FIGURE 7 Pain intensity by skin classification: community population. (a) grade 1; (b) grade 2; and (c) grades 3–4/unstageable. Reproduced from McGinnis *et al.*[45] © 2014 McGinnis *et al.*; licensee BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited.

TABLE 9 Type of pain by skin classification for the most painful torso and limb areas

Location	Skin classification	Nociceptive, *N* (%)	Neuropathic, *N* (%)	Missing, *N* (%)	Total, *N* (%)
Torso	Grade 1	3 (42.9%)	4 (57.1%)	0 (0.0%)	7 (100.0%)
	Grade 2	3 (33.3%)	6 (66.7%)	0 (0.0%)	9 (100.0%)
	Grade 3	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Grade 4	4 (80.0%)	1 (20.0%)	0 (0.0%)	5 (100.0%)
	Unstageable	0 (0.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)
	Total[a]	10 (45.5%)	12 (54.5%)	0 (0.0%)	22 (100.0%)
Limb	Grade 1	2 (50.0%)	2 (50.0%)	0 (0.0%)	4 (100.0%)
	Grade 2	1 (20.0%)	4 (80.0%)	0 (0.0%)	5 (100.0%)
	Grade 3	2 (33.3%)	3 (50.0%)	1 (16.7%)	6 (100.0%)
	Grade 4	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Unstageable	1 (33.3%)	2 (66.7%)	0 (0.0%)	3 (100.0%)
	Total[b]	6 (33.3%)	11 (61.1%)	1 (5.6%)	18 (100.0%)

a The denominator here is the number of patients who completed the LANSS for a Torso skin site.
b The denominator here is the number of patients who completed the LANSS for a Limb skin site.

Pain and pressure ulcer risk: cohort study

To explore the role of pain as a predictor of category 2 pressure ulcer development we undertook a multicentre prospective cohort study in acute and community NHS trusts.

Aims and objectives

The main aim of this study was to explore the role of pain as an early predictor of category 2 pressure ulcer development.

Objectives were to:

- assess whether the presence/absence of pressure area-related pain is a predictor of category 2 or above pressure ulcer development, after adjusting for other known variables
- explore the relationship between skin classification category and reported pain
- identify variables that are independently predictive of category 2 or above pressure ulcer development.

Methods

Study design

We undertook a multicentre prospective cohort study. We recorded the presence of key risk factors, skin status and pain at baseline with twice-weekly follow-up for up to 30 days from registration to identify the development of new category 2 or above pressure ulcers (see *Appendix 6* for the study protocol).

Setting

Hospital patients were recruited from vascular, trauma, orthopaedic and medical/elderly wards and community NHS patients were recruited from their place of normal residence (own/residential/nursing home) and community inpatient facilities.

Eligibility criteria

Inclusion criteria

Patients were eligible for study inclusion if they met all of the following criteria:

- there was evidence of acute illness through one or more of the following:
  - acute vascular, orthopaedic, medical or care of the elderly admission to secondary care hospital
  - recent hospital discharge to home/intermediate care/community care
  - existing community nursing patient with deterioration in overall condition or onset of acute illness
  - new referral to community nursing because of acute illness, deterioration in existing condition or care package breakdown
- age ≥ 18 years
- at high risk of pressure ulcer development because of one or more of the following:
  - bedfast/chairfast *and* completely immobile/very limited mobility[51]
  - localised skin pain on any pressure area skin site
  - category 1 pressure ulcer on any pressure area skin site
- able to give their written informed consent to participate
- expected to be able to comply with follow-up schedule.

Exclusion criteria

Patients were excluded from the study if one or more of the following criteria applied:

- obstetric, paediatric, day-case surgery or psychiatric patients in both acute and community settings
- unable to provide written informed consent
- unable to comply with follow-up assessment schedule
- deemed by the attending health-care professional to be too unwell to be approached and/or complete the study assessment schedule
- unable to report the presence/absence of pain (e.g. unconscious)
- with two or more category 2 or above pressure ulcers on any key pressure area skin sites (sacrum, buttocks, heels or hips).

Screening

Participating research sites were required to complete a log of all patients screened for eligibility. The following anonymised information was collected: age, gender, ethnicity and reason not eligible for study participation *or* the reason eligible but declined.

Recruitment and consent

When eligibility was indicated by the attending clinical team, patients were flagged to a member of the trust tissue viability team. A full verbal explanation of the study patient information leaflet (see *Appendix 7*) was provided for the patient to consider, including detailed information about the rationale, design and personal implications of the study. Assenting patients were then invited to provide written informed consent/witnessed consent (see *Appendix 8*) and eligibility was confirmed prior to registration using a central 24-hour telephone registration system.

Assessments

At registration, baseline demographics, skin status, pain status, analgesic use, mattress intervention, the Braden subscales[51] and risk factors, including diabetic status, presence of other chronic wounds, history of weight loss and body mass index (BMI) were recorded.

Skin status

Thirteen key skin sites (sacrum, left and right buttocks, ischial tuberosities, hips, heels, elbows and ankles) were assessed for pressure ulcers and for the presence, duration and intensity of pain. Pressure ulcers were classified as categories 1–4 or unstageable.[1] In addition, as general skin condition is predictive of category 2 pressure ulcer development,[37,57,58] observations of any alteration to intact skin (e.g. redness, scar, excoriation, dry, scaly) were recorded as 'A' and the presence of healthy skin was confirmed (see *Appendix 6*).

Pain status

To determine whether or not patients had localised skin pain on any pressure area skin site they were asked the two screening questions and, when pain was indicated, a detailed pain assessment was completed (see *Pain prevalence in hospital and community populations*, *Methods*).

Pressure ulcer interventions

All participating trusts had pressure ulcer prevention policies and guidelines, which included risk assessment, mattress and repositioning guidance. The cohort study participants received pressure ulcer prevention interventions as allocated by the attending clinical teams and as per local policies and guidelines. We recorded mattress provision, which was categorised as non-pressure relieving (e.g. domestic mattress or silicone fibre overlay), static pressure relieving (e.g. high-specification foam, viscoelastic foam, air filled, gel filled) and dynamic pressure relieving (e.g. alternating pressure, low air loss, air fluidised).

Frequency of assessments

A maximum of eight follow-up assessments were undertaken to establish the primary end point for patients who continued to be at high risk of pressure ulcer development during the 30-day period. Patients were followed up across health-care settings (i.e. hospital patients discharged home and community patients admitted to hospital) until 30 days from registration or they were assessed as being no longer at high risk, withdrawal or death. At follow-up, skin status, Braden subscales, pain status, analgesic use, mattress provision and serious adverse events were recorded.

Staff training and preparation

Consistent with methods used for the pain prevalence study, members of the tissue viability team were trained and no formal assessment of inter-rater reliability was undertaken (see *Pain prevalence in hospital and community populations*, *Methods*).

Data processing

Data processing methods were consistent with those described in *Pain prevalence in hospital and community populations* (see *Methods*). In addition, data queries and missing data were chased until the data were confirmed as correct or unavailable. Batch validation and consistency data checks were also carried out to check the accuracy of the data.

Sample size

For risk factor studies using logistic regression it is recommended that at least 10 patients with the event of interest are needed for reliable estimation of effects.[59] Our aim was to assess whether or not the presence of localised skin pain is predictive of new category 2 (or above) pressure ulcer development, after adjusting for the effects of other known risk factors.

We prespecified seven risk factors identified from our risk factor systematic review and emerging conceptual framework[46] (see *Chapter 5*): age, diabetes status, nutritional status, Braden mobility subscale score, presence of skin alterations, presence of a category 1 ulcer on any site and patient setting (hospital or community). In addition, because a patient's perception of pain is likely to be affected by the use of analgesics or other forms of pain relief, this was also included as a prespecified covariate, resulting in a model potentially including nine factors (i.e. pain, the seven prespecified risk factors and analgesic use).

A nine-factor model would therefore require a minimum of 90 patients to develop a new pressure ulcer of category 2 or above. In the absence of prospective data for community-based patient populations,[46] the sample size estimate was based on previous research in acute hospital patients,[37,58,60] suggesting that approximately 15% of patients would develop a new pressure ulcer of category 2 or above within 30 days of entering the study. Based on this assumption and allowing for potential loss to follow-up of 5%, we estimated that we would require 632 patients to be recruited to this study.

A further consideration in appraising the sample size estimate was the prevalence of pain at study entry. As no previous work in this field had been undertaken we considered a range of prevalence rates. *Table 10* shows the largest difference in pressure ulcer incidence that could be detected with a minimum of 80% power if 10% or 20% of patients reported pain at study entry. We estimated pressure ulcer event rates in the patients without pain of 10% and 15% for each case and assumed that patients with pain at study entry are more likely to develop a new ulcer than those without pain at entry.

We estimated that, if we recruited 600 patients (after accounting for 5% loss to follow up) with 60 (10%) of them having pain on study entry, this would allow us to detect a statistically significant difference ($p < 0.05$) of 13.2% between those with and those without pain using a chi-square test (80% power, 5% significance) if 10% of patients without pain and 23.2% of those with pain developed a new pressure ulcer within the 30-day follow-up period, corresponding to an odds ratio (OR) of 2.72 [95% confidence interval (CI) 1.40 to 5.27].

As this was an exploratory study and there was uncertainty around the assumptions made to estimate the sample size, the proportion of patients with pain at baseline and the incidence of pressure ulcer development was monitored by the statistical team and chief investigator and reported to a subgroup of the programme steering committee.

End point definition

The primary end point was defined as the development of a new category 2 or above pressure ulcer on any skin site after registration and before the end of follow-up. End of follow-up was defined as no longer at high risk (see *Inclusion criteria*), patient transferred to a non-participating setting, death or the end of study follow-up (30 days), whichever was the earliest event.

The secondary end point was defined as the time in days after registration to development of the first new category 2 or above pressure ulcer or to the end of follow-up for patients who were not observed to develop a new category 2 or above pressure ulcer during follow-up. Patients who were not observed to develop a new category 2 or above pressure ulcer were censored at the end of follow-up.

TABLE 10 Pain cohort study: estimation of differences detectable with 80% power

	Baseline pain		PU incidence			PU incidence		
Total *n*	With pain, *n* (%)	Without pain, *n* (%)	With pain, %	Without pain, %	Difference, %	With pain, %	Without pain, %	Difference, %
600	60 (10)	540 (90)	23.2	10.0	13.2	30.0	15.0	15.0
			OR 2.719 (95% CI 1.402 to 5.217)			OR 2.429 (CI 1.332 to 4.428)		
600	120 (20)	480 (80)	19.8	10.0	9.8	26.2	15.0	11.2
			OR 2.222 (95% CI 1.296 to 3.809)			OR 2.021 (CI 1.248 to 3.244)		

CI, confidence interval; OR, odds ratio; PU, pressure ulcer.

Analysis population

The defined analysis population was all patients for whom a primary end point could be determined, that is, patients with at least one follow-up skin assessment completed.

Analysis methods

Primary end point analysis

Univariate logistic regression was conducted to assess the candidate variables for inclusion in a multivariable model. Candidate variables were considered statistically significant if the *p*-value of the associated likelihood ratio test was < 0.1.

A multivariable analysis was then conducted to build a logistic regression model for the odds of developing a new category 2 or above pressure ulcer, using forwards and backwards stepwise variable selection. Candidate variables were included in the model if their inclusion led to a reduction in deviance with a corresponding *p*-value of < 0.1 for the associated likelihood ratio test; similarly, candidate variables were retained in the model if their exclusion led to an increase in deviance with a corresponding *p*-value of > 0.1 for the associated likelihood ratio test. The candidate variables of interest, defined at baseline (study entry) and based on a conceptual framework[46] (see *Chapter 5*), were age, diabetes status, history of weight loss, Braden mobility subscale score (category 3 or 4 vs. category 1 or 2), presence of skin alterations, presence of a category 1 pressure ulcer, setting (hospital, community), use of analgesics/pain relief and presence of pain on a skin site assessed as healthy, altered or a category 1 pressure ulcer.

The primary analysis focused on using unconditional logistic regression[61] to determine whether or not the presence or absence of pain at study entry was predictive of the development of a new category 2 or above pressure ulcer, after allowing for the other a priori factors of interest. Parameter estimates (ORs), their 95% CIs and associated *p*-values are presented. Methods for assessing the appropriateness of the model and the influence of observations were applied (e.g. the Hosmer and Lemeshow goodness of fit test[62]).

Overdispersion analysis

An additional analysis was carried out to determine if there was overdispersion in the model and, if so, whether or not this could be explained by the inclusion of other variables for which data have been collected, irrespective of whether or not the presence of pain is an important predictor of pressure ulcer development. Further variables were assessed for inclusion in the final logistic regression model obtained in the primary analysis using forwards and backwards stepwise variable selection. Candidate variables were retained in/excluded from the model if the *p*-value was < 0.1 for the associated likelihood ratio test. An assessment of whether or not the variables included in the primary analysis were still significant was also undertaken as part of the variable selection process. The other baseline candidate variables assessed for inclusion were gender, BMI, Braden scale domains (activity, friction, moisture, nutrition and sensory perception), the presence of a category 2 or above pressure ulcer, the presence of a chronic wound and mattress category.

The relationship between skin classification and the presence or absence of pain was examined using descriptive statistics (mainly cross-tabulations). Baseline data for each patient were tabulated using frequencies and summary statistics. Missing or unobtainable data were noted. Characteristics were also summarised by whether the patient presented in an acute hospital or a community setting. Correlations between the explanatory variables were also examined.

Time-to-event analysis

The relationship between presence or absence of pain at study entry and time to onset of a new category 2 or above pressure ulcer was initially investigated using Cox proportional hazards regression.[63] The assumptions of the Cox proportional hazards model were assessed using log-log plots, Cox–Snell residuals and Schoenfeld residuals and by fitting a time-dependent covariate term in the model for the presence of pain.[64] However, the proportional hazards assumptions of the model obtained did not hold and an accelerated failure time model[65] was fitted. Unlike the Cox proportional hazards model, the accelerated failure time model is a parametric model that required the distribution of the hazard function to be prespecified and, for this analysis, the gamma distribution was the most appropriate distribution. As for the logistic regression analysis, univariate analyses were conducted to determine which variables were associated with time to onset of a new category 2 or above pressure ulcer and were therefore candidates for the multivariable analyses. The final multivariable accelerated failure time model was obtained using forwards and backwards stepwise variable selection. Candidate variables were retained in/excluded from the model if the p-value was < 0.1 for the associated likelihood ratio test. The results are presented as parameter estimates (ratio of the time to onset of a category 2 or above pressure ulcer) with 95% CIs and associated p-values. The time to onset of a category 2 or above pressure ulcer was also assessed using cumulative incidence functions.

Skin site analysis

The relationship between presence or absence of pain at baseline on a healthy, altered or category 1 pressure ulcer skin site and the development of a new category 2 or above pressure ulcer at the same skin site was examined, taking account of the nesting of skin sites within patients using multilevel logistic regression (specifically, a two-level random-intercept logistic model was used). Univariate analyses and a multivariable analysis using forwards and backwards variable selection were conducted as for the primary logistic regression analysis. Candidate variables were included in the model if their inclusion led to a reduction in deviance with a corresponding p-value of < 0.1 for the associated likelihood ratio test; similarly, candidate variables were retained in the model if their exclusion led to an increase in deviance with a corresponding p-value of > 0.1 for the associated likelihood ratio test. The results are presented as parameter estimates (ORs), their 95% CIs and associated p-values.

Results

In total, 3819 patients were assessed for eligibility for the study and 634 patients were registered between 26 October 2009 and 17 November 2011. There were 26 recruiting centres across 18 NHS trusts in England, with the number of patients registered at each centre ranging from 1 to 86 (see *Appendix 1*). The centres consisted of eight teaching hospitals (four acute NHS trusts), 10 general hospitals (four acute and two community NHS trusts) and eight community care NHS trusts.

Of the 634 patients who were registered to the study, a primary end point could not be determined for 32 because they did not have any follow-up visits. Therefore, the analysis population included a total of 602 patients (*Figure 8*).

Baseline characteristics

In total, 397 (65.9%) patients were registered from the acute setting and 205 (34.1%) patients were registered from the community setting, half of whom were located in rehabilitation inpatient settings (104/205, 50.7%; *Table 11*).

Patient characteristics are detailed in *Tables 12* and *13*. In summary, across both groups there were fewer male patients (38.7%), all but one patient was Caucasian (99.8%) and one-quarter of patients were diabetic (25.4%). The median age of patients was 80 years (range 21–101 years). One-quarter of patients had a history of weight loss (24.4%), with 10.6% assessed as underweight by BMI and 22.3% assessed as obese. In total, 21.1% of patients had a chronic wound. The majority of patients recruited to the study had alterations to intact skin (62.0%), almost half had a category 1 pressure ulcer (48.2%) over one-quarter had a category 2 ulcer (27.2%) and 4.0% had a category 3, 4 or unstageable ulcer.

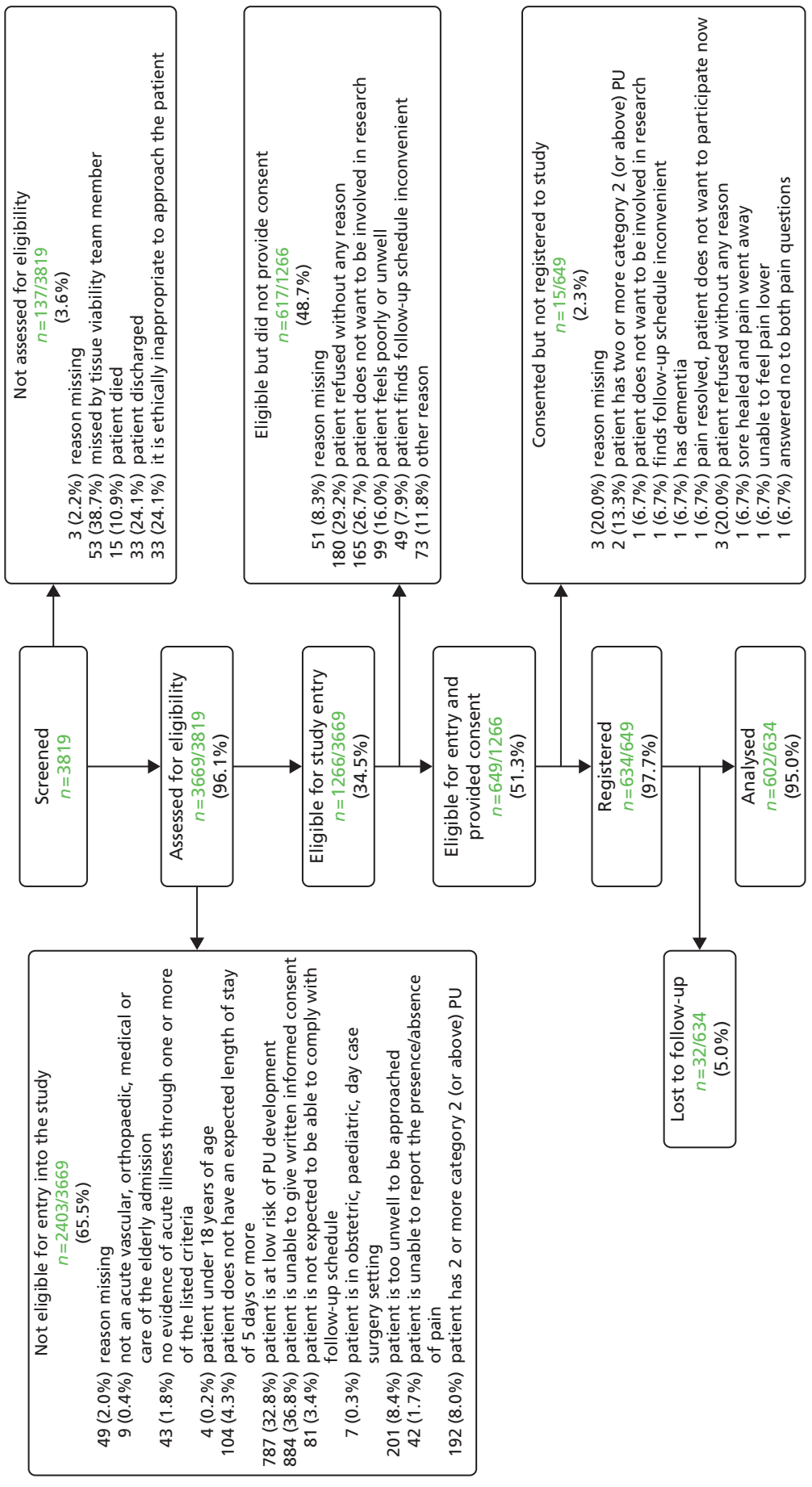

FIGURE 8 Cohort study: participant flow. PU, pressure ulcer.

TABLE 11 Pain cohort study: specialty or place assessed by setting

Specialty or place assessed	Acute ($n = 397$), *n* (%)	Community ($n = 205$), *n* (%)	Total ($n = 602$), *n* (%)
Vascular	42 (10.6)	0 (0.0)	42 (7.0)
Orthopaedic	155 (39.0)	0 (0.0)	155 (25.7)
Medical	90 (22.7)	0 (0.0)	90 (15.0)
Elderly	32 (8.1)	0 (0.0)	32 (5.3)
Medical/elderly	78 (19.6)	0 (0.0)	78 (13.0)
Patient's own home	0 (0.0)	49 (23.9)	49 (8.1)
Nursing home	0 (0.0)	27 (13.2)	27 (4.5)
Residential home	0 (0.0)	18 (8.8)	18 (3.0)
Rehabilitation unit	0 (0.0)	104 (50.7)	104 (17.3)
Other place assessed	0 (0.0)	7 (3.4)	7 (1.2)

TABLE 12 Pain cohort study: baseline characteristics by setting

Characteristic	Acute ($n = 397$)	Community ($n = 205$)	Total ($n = 602$)
Age (years)			
Mean (SD)	75.6 (12.9)	80.7 (11.7)	77.3 (12.7)
Median (range)	79 (21–101)	83 (30–100)	80 (21–101)
Sex, *n* (%)			
Male	156 (39.3)	77 (37.6)	233 (38.7)
Female	241 (60.7)	128 (62.4)	369 (61.3)
Ethnicity, *n* (%)			
Caucasian	396 (99.7)	205 (100.0)	601 (99.8)
Non-Caucasian	1 (0.3)	0 (0.0)	1 (0.2)
Is the patient diabetic, *n* (%)			
Yes	98 (24.7)	55 (26.8)	153 (25.4)
No	299 (75.3)	149 (72.7)	448 (74.4)
Missing	0 (0.0)	1 (0.5)	1 (0.2)
History of weight loss, *n* (%)			
Yes	95 (23.9)	52 (25.4)	147 (24.4)
No	302 (76.1)	152 (74.1)	454 (75.4)
Missing	0 (0.0)	1 (0.5)	1 (0.2)
BMI			
Mean (SD) (kg/m^2)	27.1 (9.3)	26.0 (9.9)	26.7 (9.5)
Median (range) (kg/m^2)	25 (11–94)	24 (11–111)	25 (11–111)
Underweight ($< 18.5\ kg/m^2$), *n* (%)	38 (9.6)	26 (12.7)	64 (10.6)
Normal weight (18.5 to $< 25\ kg/m^2$), *n* (%)	143 (36.0)	81 (39.5)	224 (37.2)
Overweight (25 to $< 30\ kg/m^2$), *n* (%)	106 (26.7)	50 (24.4)	156 (25.9)

continued

TABLE 12 Pain cohort study: baseline characteristics by setting (*continued*)

Characteristic	Acute ($n = 397$)	Community ($n = 205$)	Total ($n = 602$)
Obese (≥ 30 kg/m^2), *n* (%)	98 (24.7)	36 (17.6)	134 (22.3)
Missing, *n* (%)	12 (3.0)	12 (5.9)	24 (4.0)
Chronic wounds, *n* (%)			
Yes	75 (18.9)	52 (25.4)	127 (21.1)
No	322 (81.1)	152 (74.1)	474 (78.7)
Missing	0 (0.0)	1 (0.5)	1 (0.2)
Skin alterations at baseline, *n* (%)			
Yes	242 (61.0)	131 (63.9)	373 (62.0)
No	155 (39.0)	74 (36.1)	229 (38.0)
Category 1 at baseline, *n* (%)			
Yes	198 (49.9)	92 (44.9)	290 (48.2)
No	199 (50.1)	113 (55.1)	312 (51.8)
Existing category or above at baseline, *n* (%)			
Yes	116 (29.2)	48 (23.4)	164 (27.2)
No	281 (70.8)	157 (76.6)	438 (72.8)
Pain at a healthy, altered or category 1 skin site, *n* (%)			
Yes	301 (75.8)	163 (79.5)	464 (77.1)
No	96 (24.2)	42 (20.5)	138 (22.9)
Worst skin status at baseline, *n* (%)			
Healthy intact skin	45 (11.3)	25 (12.2)	70 (11.6)
Alterations to intact skin	99 (24.9)	55 (26.8)	154 (25.6)
Category 1	137 (34.5)	77 (37.6)	214 (35.5)
Category 2	98 (24.7)	42 (20.5)	140 (23.3)
Category 3	10 (2.5)	3 (1.5)	13 (2.2)
Category 4	2 (0.5)	2 (1.0)	4 (0.7)
Unstageable	6 (1.5)	1 (0.5)	7 (1.2)
Analgesic use, *n* (%)			
Yes	366 (92.2)	182 (88.8)	548 (91.0)
No	31 (7.8)	23 (11.2)	54 (9.0)
Mattress category, *n* (%)			
Non-pressure relieving	5 (1.3)	31 (15.1)	36 (6.0)
Static pressure-relieving	168 (42.3)	105 (51.2)	273 (45.3)
Dynamic pressure-relieving	224 (56.4)	68 (33.2)	292 (48.5)
Missing	0 (0.0)	1 (0.5)	1 (0.2)

TABLE 13 Pain cohort study: baseline characteristics by setting – Braden subscales

Braden subscale	Acute ($n = 397$), *n* (%)	Community ($n = 205$), *n* (%)	Total ($n = 602$), *n* (%)
Sensory perception			
Very limited	5 (1.3)	3 (1.5)	8 (1.3)
Slightly limited	68 (17.1)	15 (7.3)	83 (13.8)
No impairment	324 (81.6)	187 (91.2)	511 (84.9)
Moisture			
Constantly moist	2 (0.5)	3 (1.5)	5 (0.8)
Very moist	25 (6.3)	13 (6.3)	38 (6.3)
Occasionally moist	105 (26.4)	55 (26.8)	160 (26.6)
Rarely moist	265 (66.8)	134 (65.4)	399 (66.3)
Activity			
Bedfast	96 (24.2)	8 (3.9)	104 (17.3)
Chairfast	221 (55.7)	92 (44.9)	313 (52.0)
Walks occasionally	76 (19.1)	81 (39.5)	157 (26.1)
Walks frequently	4 (1.0)	24 (11.7)	28 (4.7)
Mobility			
Completely immobile	9 (2.3)	12 (5.9)	21 (3.5)
Very limited	204 (51.4)	58 (28.3)	262 (43.5)
Slightly limited	142 (35.8)	89 (43.4)	231 (38.4)
No limitation	42 (10.6)	46 (22.4)	88 (14.6)
Nutrition			
Very poor	13 (3.3)	6 (2.9)	19 (3.2)
Probably inadequate	130 (32.7)	28 (13.7)	158 (26.2)
Adequate	163 (41.1)	95 (46.3)	258 (42.9)
Excellent	91 (22.9)	76 (37.1)	167 (27.7)
Friction and shear			
Problem	62 (15.6)	39 (19.0)	101 (16.8)
Potential problem	295 (74.3)	118 (57.6)	413 (68.6)
No apparent problem	40 (10.1)	48 (23.4)	88 (14.6)
Total score			
At risk (≤ 18)	324 (81.6)	115 (56.1)	439 (72.9)
Not at risk (> 18)	73 (18.4)	90 (43.9)	163 (27.1)

Pain was reported on healthy, altered and category 1 skin sites by 77.1% of patients (see *Table 12*). Only 3.5% of patients were completely immobile, with the majority of patients assessed as having either very limited (43.5%) or slightly limited (38.4%) mobility according to the Braden mobility subscale (see *Table 13*).

The majority of patients were receiving either a static pressure-relieving (45.3%) or a dynamic pressure-relieving (48.5%) mattress. In the community 15.1% of mattresses were described as non-pressure relieving whereas in the hospital setting this was the case for only 1.3% of patients (see *Table 12*).

Primary end point analysis

The primary end point was whether or not a patient developed a new category 2 or above pressure ulcer on any skin site after registration and before the end of follow-up. Skin sites with a category 2 or above pressure ulcer or recorded as not applicable/unable to assess (e.g. amputated limb or bandage/dressing in situ) at baseline were excluded from the primary end point analysis. The overall incidence of new category 2 or above pressure ulcers in the analysis population was 152 out of 602 (25.2%).

A total of 464 (77.1%) of the study population reported pressure area pain on skin assessed clinically as normal, altered or with a category 1 pressure ulcer and, of these, 130 (28.0%) developed a category 2 (or above) pressure ulcer compared with 22 (15.9%) patients with no pain at baseline (*Table 14*).

TABLE 14 Pain cohort study: baseline characteristics by pressure ulcer development

Characteristic	Develops new PU ($n = 152$)	Does not develop new PU ($n = 450$)	Total ($n = 602$)
Age			
Mean (SD) (years)	78.1 (12.0)	77.1 (13.0)	77.3 (12.7)
Median (range) (years)	81 (25–99)	80 (21–101)	80 (21–101)
< 65 years, *n* (%)	21 (22.1)	74 (77.9)	95 (15.8)
65–74 years, *n* (%)	29 (25.4)	85 (74.6)	114 (18.9)
75–84 years, *n* (%)	51 (24.9)	154 (75.1)	205 (34.1)
≥ 85 years, *n* (%)	51 (27.1)	137 (72.9)	188 (31.2)
Sex, *n* (%)			
Male	68 (29.2)	165 (70.8)	233 (38.7)
Female	84 (22.8)	285 (77.2)	369 (61.3)
Ethnicity, *n* (%)			
Caucasian	151 (25.1)	450 (74.9)	601 (99.8)
Non-Caucasian	1 (100.0)	0 (0.0)	1 (0.2)
Is the patient diabetic, *n* (%)			
Yes	47 (30.7)	106 (69.3)	153 (25.4)
No	105 (23.4)	343 (76.6)	448 (74.4)
Missing	0 (0.0)	1 (100.0)	1 (0.2)
History of weight loss, *n* (%)			
Yes	38 (25.9)	109 (74.1)	147 (24.4)
No	114 (25.1)	340 (74.9)	454 (75.4)
Missing	0 (0.0)	1 (100.0)	1 (0.2)

TABLE 14 Pain cohort study: baseline characteristics by pressure ulcer development (*continued*)

Characteristic	Develops new PU ($n = 152$)	Does not develop new PU ($n = 450$)	Total ($n = 602$)
BMI			
Mean (SD) (kg/m^2)	27.0 (10.0)	26.6 (9.3)	26.7 (9.5)
Median (range) (kg/m^2)	25 (11–91)	25 (11–111)	25 (11–111)
Underweight (< 18.5 kg/m^2), *n* (%)	16 (25.0)	48 (75.0)	64 (10.6)
Normal weight (18.5 to < 25 kg/m^2), *n* (%)	61 (27.2)	163 (72.8)	224 (37.2)
Overweight (25 to < 30 kg/m^2), *n* (%)	30 (19.2)	126 (80.8)	156 (25.9)
Obese (≥ 30 kg/m^2), *n* (%)	38 (28.4)	96 (71.6)	134 (22.3)
Missing, *n* (%)	7 (29.2)	17 (70.8)	24 (4.0)
Chronic wounds, *n* (%)			
Yes	45 (35.4)	82 (64.6)	127 (21.1)
No	107 (22.6)	367 (77.4)	474 (78.7)
Missing	0 (0.0)	1 (100.0)	1 (0.2)
Skin alterations at baseline, *n* (%)			
Yes	109 (29.2)	264 (70.8)	373 (62.0)
No	43 (18.8)	186 (81.2)	229 (38.0)
Category 1 at baseline, *n* (%)			
Yes	105 (36.2)	185 (63.8)	290 (48.2)
No	47 (15.1)	265 (84.9)	312 (51.8)
Existing category 2 or above at baseline, *n* (%)			
Yes	54 (32.9)	110 (67.1)	164 (27.2)
No	98 (22.4)	340 (77.6)	438 (72.8)
Pain at a healthy, altered or category 1 skin site, *n* (%)			
Yes	130 (28.0)	334 (72.0)	464 (77.1)
No	22 (15.9)	116 (84.1)	138 (22.9)
Analgesic use, *n* (%)			
Yes	137 (25.0)	411 (75.0)	548 (91.0)
No	15 (27.8)	39 (72.2)	54 (9.0)
Braden mobility subscale, *n* (%)			
Completely immobile	5 (23.8)	16 (76.2)	21 (3.5)
Very limited	61 (23.3)	201 (76.7)	262 (43.5)
Slightly limited	63 (27.3)	168 (72.7)	231 (38.4)
No limitation	23 (26.1)	65 (73.9)	88 (14.6)
Setting, *n* (%)			
Acute	98 (24.7)	299 (75.3)	397 (65.9)
Community	54 (26.3)	151 (73.7)	205 (34.1)

PU, pressure ulcer.

The results of the univariate analysis are presented in *Table 15*. Factors that had a statistically significant association with the odds of developing a new category 2 or above pressure ulcer included presence of skin alterations (OR 1.79, 95% CI 1.20 to 2.66; $p = 0.0045$), presence of at least one category 1 pressure ulcer (OR 3.20, 95% CI 2.63 to 4.74; $p < 0.0001$) and presence of pain on a healthy, altered or category 1 skin site at baseline (OR 2.05, 95% CI 1.25 to 3.38; $p = 0.0047$). There was marginal evidence that diabetic status was associated with the odds of developing a new category 2 or above pressure ulcer, with the odds higher for patients with diabetes than for patients without diabetes (OR 1.45, 95% CI 0.97 to 2.18; $p = 0.0722$). The following factors were not statistically significant: age, history of previous weight loss, Braden mobility subscale score, setting and analgesic use. Therefore, there was no evidence of an association between these factors and the odds of developing a new category 2 or above pressure ulcer.

TABLE 15 Pain cohort study: results of the univariate analysis of the odds of developing a category 2 or above pressure ulcer

Covariate	OR	95% CI	*p*-value
Age (continuous)	1.01	0.99 to 1.022	0.3936
Age (categorical) (reference = '< 65 years')			
≥ 85 years	1.31	0.73 to 2.35	0.4192
65–74 years	1.20	0.63 to 2.29	0.3885
75–84 years	1.17	0.65 to 2.08	0.2996
Diabetic status[a] (yes vs. no)	1.45	0.97 to 2.18	0.0722
History of weight loss[b] (yes vs. no)	1.04	0.68 to 1.60	0.8462
Braden mobility subscale score (1 or 2 vs. 3 or 4)	1.21	0.84 to 1.76	0.3055
Skin alterations (yes vs. no)	1.79	1.20 to 2.66	0.0045
Category 1 PU (yes vs. no)	3.20	2.63 to 4.74	< 0.0001
Setting (acute vs. community)	0.92	0.62 to 1.35	0.6576
Analgesic use (yes vs. no)	0.87	0.46 to 1.62	0.6542
Pain on healthy, altered or category 1 skin site (yes vs. no)	2.05	1.25 to 3.38	0.0047
Covariates considered for overdispersion analysis			
Gender (female vs. male)	0.72	0.49 to 1.04	0.0780
BMI (continuous)	1.00	0.99 to 1.02	0.6702
Braden sensory subscale (reference = no impairment)			
Slightly limited	0.92	0.54 to 1.58	0.6886
Very limited	0.41	0.05 to 3.40	
Braden moisture subscale (reference = rarely moist)			
Occasionally moist	1.83	1.22 to 2.74	0.0277
Very moist	1.11	0.51 to 2.44	
Constantly moist	2.39	0.39 to 14.55	
Braden activity subscale (reference = bedfast)			
Chairfast	1.83	1.05 to 3.19	0.0775
Walks occasionally	1.43	0.77 to 2.65	
Walks frequently	0.75	0.23 to 2.40	

TABLE 15 Pain cohort study: results of the univariate analysis of the odds of developing a category 2 or above pressure ulcer (*continued*)

Covariate	OR	95% CI	*p*-value
Braden nutrition subscale (reference = excellent)			
Adequate	0.93	0.59 to 1.47	0.6058
Probably inadequate	1.26	0.77 to 2.06	
Very poor	1.10	0.37 to 3.23	
Braden friction and shear subscale (reference = no apparent problem)			
Potential problem	1.06	0.62 to 1.82	0.8036
Problem	1.22	0.64 to 2.36	
Mattress category (reference = dynamic high-risk pressure relieving)			
Static risk pressure relieving	1.28	0.87 to 1.87	0.2430
Non-pressure relieving	0.95	0.41 to 2.17	
Chronic wound	1.89	1.24 to 2.88	0.0032
Category 2 or above PU	1.70	1.15 to 2.53	0.0083

PU, pressure ulcer.
a Missing diabetic status set to 'no' for one missing patient.
b Missing history of weight loss status set to 'no' for one missing patient.

The final multivariable model obtained from the variable selection carried out included three variables: the presence of a category 1 pressure ulcer (OR 3.25, 95% CI 2.17 to 4.86; $p < 0.0001$), the presence of skin alterations (OR 1.98, 95% CI 1.30 to 3.00; $p = 0.0014$) and the presence of pain on a healthy, altered or category 1 skin site at baseline (OR 1.56, 95% CI 0.93 to 2.63; $p = 0.0931$) (*Table 16*). Therefore, there was significant evidence that the presence of a category 1 pressure ulcer and presence of skin alterations are risk factors for developing a category 2 or above ulcer. After adjusting for these risk factors, there was marginal evidence that the presence of pain is a further risk factor for developing a category 2 or above pressure ulcer.

Overdispersion analysis

The model obtained in the primary end point analysis was further developed by considering the inclusion of other variables for which data were collected using further forwards and backwards stepwise variable selection. The results of the univariate analyses are shown in *Table 15*.

TABLE 16 Pain cohort study: final model for the odds of developing a category 2 or above pressure ulcer ($n = 602$)

Covariate	OR	95% CI	*p*-value
Category 1 PU (yes vs. no)	3.25	2.17 to 4.86	< 0.0001
Skin alterations (yes vs. no)	1.98	1.30 to 3.00	0.0014
Pain on healthy, altered or category 1 skin site (yes vs. no)	1.56	0.93 to 2.63	0.0931

PU, pressure ulcer.

The final multivariable model obtained from the further variable selection carried out included six variables. These included (1) the presence of a category 1 pressure ulcer (OR 3.20, 95% CI 2.11 to 4.85; $p < 0.0001$), (2) the presence of skin alterations (OR 1.90, 95% CI 1.24 to 2.91; $p = 0.0032$), (3) the presence of pain on a healthy, altered or category 1 skin site at baseline (OR 1.85, 95% CI 1.07 to 3.20; $p = 0.0271$), (4) the presence of a category 2 ulcer (OR 2.09, 95% CI 1.35 to 3.23; $p = 0.0009$), (5) the presence of a chronic wound (OR 1.66, 95% CI 1.04 to 2.62, $p = 0.0277$; *Table 17*). In addition, (6) there was significant evidence that Braden activity was related to the odds of developing a new category 2 or above pressure ulcer ($p = 0.0476$). As shown in *Table 17*, the odds of developing a category 2 or above ulcer were greater for patients who were chairfast than for patients who were bedfast (OR 1.86, 95% CI 1.03 to 2.29) whereas there was no evidence that patients who walk occasionally or frequently were more likely to develop a category 2 or above pressure ulcer than patients who were bedfast (the 95% CIs for the ORs straddle 1). After adjusting for these risk factors, there was significant evidence that the presence of pain is a further risk factor for developing a category 2 or above pressure ulcer.

Correlations between explanatory variables were examined and each of the comparisons yielded low associations. *Table 18* shows the associations between the explanatory variables. Cross-tabulations of explanatory variables were also produced for further information and are shown in *Appendix 9*.

Time-to-event analysis

The variables that were statistically significantly (at the 10% level) associated with the time to onset of a new category 2 or above pressure ulcer in the univariate analyses were age [acceleration factor (AF) 1.01, 95% CI 1.00 to 1.03; $p = 0.0354$], Braden mobility subscale score (AF 1.37, 95% CI 1.00 to 1.87; $p = 0.0498$), the presence of a category 1 pressure ulcer (AF 2.63, 95% CI 1.93 to 3.58; $p < 0.0001$) and the presence of pain on a healthy, altered or category 1 skin site (AF 2.68, 95% CI 1.86 to 3.86; $p < 0.0001$). In addition, there was marginal evidence that the presence of skin alterations was associated with the time to onset of a new category 2 or above pressure ulcer (AF 1.40, 95% CI 0.99 to 1.97; $p = 0.0593$; *Table 19*).

TABLE 17 Pain cohort study: final model for the odds of developing a category 2 or above pressure ulcer from the overdispersion analysis ($n = 602$)

Covariate	OR	95% CI	*p*-value
Category 1 PU	3.20	2.11 to 4.85	< 0.0001
Skin alterations	1.90	1.24 to 2.91	0.0032
Pain on a healthy, altered or category 1 skin site	1.85	1.07 to 3.20	0.0271
Category 2 PU	2.09	1.35 to 3.23	0.0009
Braden activity: chairfast vs. bedfast	1.86	1.03 to 3.36	0.0476
Braden activity: walks occasionally vs. bedfast	1.19	0.62 to 2.29	
Braden activity: walks frequently vs. bedfast	0.71	0.21 to 2.46	
Chronic wound	1.66	1.06 to 2.62	0.0277

PU, pressure ulcer.

TABLE 18 Pain cohort study: associations between explanatory variables

Explanatory variable 1	Explanatory variable 2	Correlation coefficient	Level of association
Category 1 PU	Skin alterations	–0.07	Low
Category 1 PU	Pain on a category 0, 1 or A skin site	0.19	Low
Category 1 PU	Category 2 PU	–0.02	Low
Category 1 PU	Braden activity	–0.01	Low
Category 1 PU	Chronic wound	0.09	Low
Skin alterations	Pain on a category 0, 1 or A skin site	0.11	Low
Skin alterations	Category 2 PU	–0.02	Low
Skin alterations	Braden activity	–0.10	Low
Skin alterations	Chronic wound	0.07	Low
Pain on a category 0, 1 or A skin site	Category 2 PU	–0.21	Low
Pain on a category 0, 1 or A skin site	Braden activity	–0.16	Low
Pain on a category 0, 1 or A skin site	Chronic wound	0.07	Low
Category 2 PU	Braden activity	–0.02	Low
Category 2 PU	Chronic wound	0.04	Low
Braden activity	Chronic wound	–0.15	Low

PU, pressure ulcer.

TABLE 19 Pain cohort study: univariate analyses for time to onset of a category 2 or above pressure ulcer

Factor	Ratio[a] of time to develop new category 2 or above PU	95% CI	*p*-value
Age (continuous)	1.01	1.00 to 1.03	0.0354
Skin alterations (yes vs. no)	1.40	0.99 to 1.97	0.0593
Analgesic use (yes vs. no)	1.05	0.61 to 1.83	0.8577
Braden mobility (1 or 2 vs. 3 or 4)	1.37	1.00 to 1.87	0.0498
Category 1 PU (yes vs. no)	2.63	1.93 to 3.58	< 0.0001
Diabetic (yes vs. no)	1.24	0.85 to 1.80	0.2591
History of previous weight loss (yes vs. no)	0.90	0.62 to 1.30	0.5715
Pain (yes vs. no)	2.68	1.86 to 3.86	< 0.0001
Setting (acute vs. community)	1.13	0.81 to 1.58	0.4652

PU, pressure ulcer.
a Ratio corresponds to the AF.

The final accelerated failure time multivariable model obtained from forwards and backwards variable selection included the covariates presence of a category 1 pressure ulcer and presence of pain on a healthy, altered or category 1 skin site and so both are risk factors for reducing the time to develop a category 2 or above pressure ulcer (*Table 20*). Unlike the primary analysis, the presence of skin alterations has not been included in the final model but was shown to have a significant association with time to onset of a new category 2 or above pressure ulcer in the univariate analysis and therefore may explain why skin alterations were not included in the final model. The cumulative incidence function for the presence of skin alterations is very similar to the cumulative incidence function for the presence of pain on a healthy, altered or category 1 pressure ulcer skin site, although the cumulative incidence functions indicate that there is a larger difference between pain categories than between skin alteration categories. The final model shows that patients are likely to develop a new category 2 or above pressure ulcer 2.32 times faster if they have a category 1 pressure ulcer at baseline than if they do not have a category 1 pressure ulcer at baseline (AF 2.32, 95% CI 1.73 to 3.12; $p < 0.0001$). In addition, patients are likely to develop a new category 2 or above pressure ulcer 2.28 times faster if they have pressure area-related pain at a healthy, altered or category 1 skin site than if they do not have pressure area-related pain at a healthy, altered or category 1 skin site (AF 2.28, 95% CI 1.59 to 3.27; $p < 0.0001$).

Cumulative incidence functions for the presence of skin alterations, the presence of a category 1 pressure ulcer and the presence of pain on a healthy, altered or category 1 skin site at baseline are presented in *Figure 9*.

Skin site-level analysis

The analysis population of 602 patients had a combined total of 7863 potential skin sites assessed (*Table 21*), of which the majority (77.5%) were observed as being healthy skin sites. Pain was reported more frequently with more severe skin status, that is, 63.1% of category 1 skin sites were observed to have pain compared with 40.3% of skin sites with alterations and 6.4% of healthy skin sites (see *Table 21*).

Of the total 7863 skin sites, 7483 (95.2%) were evaluable in the analysis, that is, all skin sites that were observed as being healthy, altered or category 1 at baseline and which had at least one follow-up assessment (i.e. the end point could be derived for that skin site). Overall, 223 (3.0%) of the evaluable skin sites developed a new category 2 or above pressure ulcer, and the incidence for skin sites with pain at baseline was higher at 10.3% than that for skin sites with no pain at baseline (1.7%) (*Table 22*). Similarly, the incidence of a new category 2 or above pressure ulcer was observed to increase with the severity of skin status at baseline (i.e. the incidence for skin sites with a category 1 pressure ulcer at baseline was 18.2% compared with 6.4% for sites with skin alterations and 1.1% for healthy skin sites at baseline).

TABLE 20 Pain cohort study: final model for time to onset of a category 2 or above pressure ulcer ($n = 602$)

Factor	Ratio[a] of time to develop new category 2 or above PU	95% CI	*p*-value
Category 1 PU (yes vs. no)	2.32	1.73 to 3.12	< 0.0001
Pain (yes vs. no)	2.28	1.59 to 3.27	< 0.0001

PU, pressure ulcer.
a Ratio corresponds to the AF.

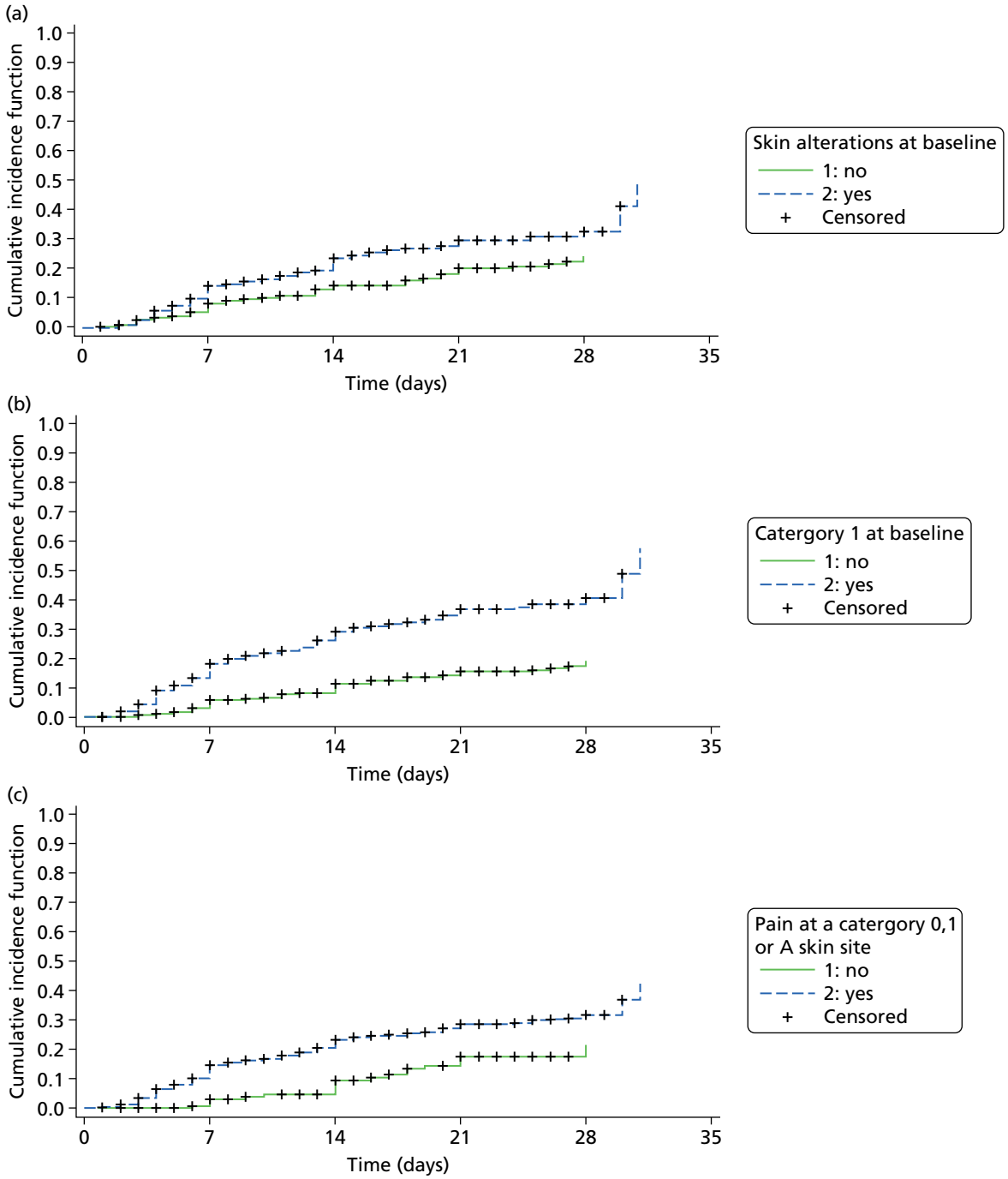

FIGURE 9 Cumulative incidence plots. (a) Cumulative incidence plot of time to develop a new category 2 pressure ulcer by presence of skin alterations at baseline; (b) cumulative incidence plot of time to develop a new category 2 pressure ulcer by presence of a category 1 PU at baseline; and (c) cumulative incidence plot of time to develop a new category 2 pressure ulcer by presence of pain on a healthy, altered or category 1 pressure ulcer skin site at baseline.

TABLE 21 Baseline skin and pain assessment for all skin sites

Skin classification	Pain yes, *n* (%)	Pain no, *n* (%)	Missing, *n* (%)	Total, *n* (%)
Normal skin	390 (6.4)	5700 (93.5)	6 (0.1)	6096 (77.5)
Skin alterations	342 (40.3)	504 (59.4)	3 (0.4)	849 (10.8)
Category 1	351 (63.1)	205 (36.9)	0 (0.0)	556 (7.1)
Category 2	116 (78.4)	32 (21.6)	0 (0.0)	148 (1.9)
Category 3	13 (100.0)	0 (0.0)	0 (0.0)	13 (0.2)
Category 4	3 (75.0)	1 (25.0)	0 (0.0)	4 (0.1)
Unstageable	6 (85.7)	1 (14.3)	0 (0.0)	7 (0.1)
Unable to assess	6 (7.6)	52 (65.8)	21 (26.6)	79 (1.0)
Not applicable	2 (2.3)	26 (29.9)	59 (67.8)	87 (1.1)
Other wound	0 (0.0)	6 (85.7)	1 (14.3)	7 (0.1)
Classification missing	0 (0.0)	0 (0.0)	17 (100.0)	17 (0.2)
Total	1229 (15.6)	6527 (83.0)	107 (1.4)	7863 (100.0)

Note
602 patients. Each patient had 13 skin assessments and there were 37 'other' sites assessed. The overall total therefore corresponds to (602 × 13) + 37 = 7863 skin assessments.

TABLE 22 Pain and skin status by category 2 or above pressure ulcer development

Variable	New PU (*n* = 223, 3.0%), *n* (%)	No new PU (*n* = 7260, 97%), *n* (%)	Total (*n* = 7483), *n* (%)
Pain			
Yes	111 (10.3)	966 (89.7)	1077 (14.4)
No	112 (1.7)	6294 (98.3)	6406 (85.6)
Skin status			
Healthy intact skin	68 (1.1)	6014 (98.9)	6082 (81.3)
Alterations to intact skin	54 (6.4)	792 (93.6)	846 (11.3)
Category 1	101 (18.2)	454 (81.8)	555 (7.4)

PU, pressure ulcer.

The results of the univariate analysis are presented in *Table 23*. Factors that had a statistically significant association with the odds of developing a new category 2 or above pressure ulcer were skin status, which consisted of two levels – skin alterations (OR 6.29, 95% CI 4.21 to 9.40; $p < 0.0001$) and category 1 pressure ulcer (OR 27.34, 95% CI 18.5 to 40.4; $p < 0.0001$) – and the presence of pain at baseline on a healthy, altered or category 1 skin site (OR 8.68, 95% CI 6.30 to 11.97; $p < 0.0001$). The following factors were not statistically significant: age, diabetic status, history of previous weight loss, Braden mobility subscale score, setting and analgesic use. Therefore, there was no evidence of an association between these factors and the odds of developing a new category 2 or above pressure ulcer at the skin site level.

The final multivariable model obtained from the variable selection carried out included two variables: skin status, which consisted of two levels – skin alterations (OR 4.65, 95% CI 3.01 to 7.18; $p < 0.0001$) and category 1 pressure ulcer (OR 17.30, 95% CI 11.09 to 27.00; $p < 0.0001$) – and the presence of pain on a healthy, altered or category 1 skin site (OR 2.25, 95% CI 1.53 to 3.29; $p < 0.0001$; *Table 24*). Therefore, there was significant evidence that skin status is a risk factor for developing a category 2 or above pressure ulcer after adjusting for between-patient variation. After adjusting for skin status and between-patient variation there was strong evidence that the presence of pain is a further risk factor for developing a category 2 or above pressure ulcer.

TABLE 23 Pain cohort study: results of the univariate analysis of the odds of developing a category 2 or above pressure ulcer at the skin site level

Covariate	OR	95% CI	*p*-value
Age (continuous)	1.01	0.99 to 1.02	0.4808
Diabetic status[a] (no vs. yes)	0.81	0.54 to 1.21	0.3070
History of weight loss[b] (no vs. yes)	1.03	0.68 to 1.57	0.8914
Braden mobility subscale score (1 or 2 vs. 3 or 4)	1.14	0.80 to 1.64	0.4714
Skin status (reference = healthy skin)			
Skin alterations	6.29	4.21 to 9.40	< 0.0001
Category 1 PU	27.34	18.5 to 40.4	< 0.0001
Setting (acute vs. community)	0.91	0.63 to 1.32	0.6148
Analgesic use (no vs. yes)	1.33	1.74 to 2.39	0.3350
Pain on healthy, altered or category 1 skin site (yes vs. no)	8.68	6.30 to 11.97	< 0.0001

PU, pressure ulcer.
a Missing diabetic status set to 'no' for one missing patient.
b Missing history of weight loss status set to 'no' for one missing patient.

TABLE 24 Pain cohort study: final model for the odds of developing a category 2 or above pressure ulcer at the skin site level ($n = 602$, $n = 7483$ skin sites)

Covariate	OR	95% CI	*p*-value
Skin status (reference = healthy skin)			
Skin alterations	4.65	3.01 to 7.18	< 0.0001
Category 1 PU	17.30	11.09 to 27.00	< 0.0001
Pain (yes vs. no)	2.25	1.53 to 3.29	< 0.0001

PU, pressure ulcer.
Note
602 patients. There were a total of 7483 evaluable skin sites in the analysis (a skin site was considered evaluable if it was observed as being healthy, altered or category 1 at baseline and had at least one follow-up assessment (i.e. the end point could be derived for that skin site).

Discussion

The prevalence studies are the first to assess pressure area-related pain in large representative hospital and community populations. In the hospital population, of 2010 patients asked the pain screening questions, 327 indicated that they had pain on one or more pressure areas (skin site not recorded), providing an overall unattributed pressure area-related pain prevalence of 16.3%. The importance of the inclusion of patients without pressure ulcers is emphasised by the finding that 12.6% (223/1769) of hospital patients without pressure ulcers reported pressure area-related pain.[35] There are no other published reports of this type of pain. The prevalence of unattributed pressure area-related pain in patients with pressure ulcers was 43.2% (104/241) in hospital patients and 75.6% (133/176) in community patients. This is similar to the results of other smaller studies reporting pressure ulcer pain prevalence, with prevalence ranging from 37% to 100%,[40–43,66,67] and is comparable to the prevalence of pain in other chronic wounds in European populations.[43,68–70]

The detailed pain assessment of 160 hospital and 37 community patients identified pressure area-related pain on skin areas assessed as normal as well as on all grades of pressure ulcer. 'The distribution of pain

intensity measured using a 0–10 nominal rating scale was similar for all grades, which is consistent with pain intensity in other disease states, where the severity of illness is not necessarily related to patients' reports of pain intensity.[68,71]

It is noteworthy that in the community patient population, none of the patients reported pressure area related pain on a skin site assessed as normal'[45] whereas, of the 75 hospital detailed pain assessment patients with a pressure ulcer, 30 (40%) did report pressure area-related pain on a skin site assessed as normal.

The dominant type of pain in hospital patients was inflammatory pain (70.3% torso and 60.3% limb skin sites) whereas in the community patients neuropathic pain was dominant (54.5% torso and 61.1% limb skin sites). This is consistent with the prevalence of neuropathic pain in leg ulcer patients. For example, in a prospective longitudinal cohort study of painful leg ulceration, 43.5% of respondents ($n = 96$) reported neuropathic pain.[68] It is noteworthy that both inflammatory and neuropathic pain was observed for normal skin and all grades of pressure ulcer for both hospital and community patients. We did not record the duration of the pain or pressure ulcer and this may be related to the type of pain and is an area of further study.

The 'limitations of the overall pain prevalence estimate of unattributed pain are that: skin assessment data were recorded by clinical staff, which has inherent limitations[37,56,72] and may have resulted in over or under-reporting of pressure ulcers or misclassification of Grade or extent of tissue damage, particularly at Grade 1, which is prone to misclassification;'[45,56] the pain prevalence data were recorded at the patient level and not by skin site; we were not able to record pain treatment and therefore the quality of pain management may differ between wards/hospital/community settings and impact on pain reports; and the methodology used meant that a significant proportion of hospital (40.8%) and community (38.7%) patients were not able to participate in the pain prevalence study because of illness (too unwell, end of life, unconscious), difficulty in assessing pain (confused or communication difficulty) or unavailability (unable to disturb, off the ward, in isolation).

Prevalence studies provide a good measure of the extent of chronic long-lived disease and are less reliable in the measurement of short-lived disease. Both pressure ulcers and pain can be both long-lived and short-lived and as such there are general limitations associated with prevalence estimates for these conditions. In the hospital population, pressure ulcer prevalence rates are affected by staff training and awareness, admission/discharge rates and case mix, and in the interpretation of hospital prevalence rates these factors need to be taken into account.[2,73–75]

'Prevalence studies in the community are challenging and time-consuming to undertake. Few have been undertaken[4,76,77] and the true extent of the pressure ulcer problem at a population level is not well quantified. In this study, in two localities in the North of England we report a prevalence . . . of 0.77 people with pressure ulcers per 1000 adult population [locality 1] and . . . 0.40 per 1000 adult population [locality 2]. The prevalence rates are similar to those reported by Vowden and Vowden,[4] who reported a community prevalence rate of 0.66 per adult population.'[47]

'Several previous studies have reviewed the methods for data collection for determining pressure ulcer prevalence and incidence.[2,73,74] This study provides further evidence that different methods used for case ascertainment result in potentially important variations in the prevalence reported. Locality 1 collected data for a much larger group of patients where pressure ulcer status not considered prior to assessment, whereas locality 2 collected data only for patients known to have a pressure ulcer.'[47] A notable difference between the two localities resulting from the different method applied was the location of patients assessed. In locality 1, 50.3% of patients were in nursing homes, whereas in locality 2 only 4.9% of patients were in nursing homes. 'As indicated in the methodology section, in the UK, nursing homes would normally treat patients with pressure ulcers themselves and only patients with complex wounds are referred to the community nursing service.'[48] In locality 1 all nursing home residents were included

in the prevalence study whereas in locality 2 only those patients known to community nursing services were included, 'highlighting the importance of clear methodological descriptions and effective case ascertainment for study comparison and establishing the true prevalence of pressure ulcers' in a community setting.[48]

Our sample size estimates were based on limited pressure ulcer pain prevalence data,[2,15] with no available data for grade 1 or normal skin. The prevalence rates observed were much higher than those estimated in patients with grade 1 and normal skin. In addition, the sample size calculation planned for the inclusion of 6000 patients from two community NHS trusts. However, this was an approximation as estimating the denominator population for these trusts was difficult as no data were available regarding the number of patients on the community nursing caseload. As a result of this and because of differences in the implementation of pressure ulcer prevalence audit methods in the two localities, the number of community patients included in the prevalence audit was significantly less than planned: locality 1 audited 1680 patients including those on the community nursing caseload and in nursing homes, residential homes and palliative care environments, whereas locality 2 audited only those 102 patients who were on the community nursing caseload and were known to have a pressure ulcer. In addition, both community trusts asked the pain questions only of those patients with pressure ulcers, whereas in the acute trusts the pain questions were asked of all patients, regardless of whether or not they had a pressure ulcer. As a result, 2010 patients were asked the pain questions in the acute trusts compared with 176 in the community trusts. Because of the differing methodologies employed by the acute and community trusts, the two populations cannot be combined and therefore the confidence boundaries for the overall unattributed pressure area-related pain prevalence provided in the sample size calculation have been updated post hoc for the two settings. The hospital patient population of 2010 patients allows us to estimate the unattributed pressure area-related pain prevalence of 16.3% to within ±1.7%. The community sample of 176 patients allows us to estimate the unattributed pressure area-related pain prevalence of 75.6% to within ±6.4%.

Cohort study

The pain cohort study is the first risk factor study to investigate the role of pain as a factor independently predictive of subsequent category 2 (or above) pressure ulcer development. It found that pain was an independent predictor of category 2 (or above) pressure ulcer development in high-risk hospital and community patients with acute illness.

Building on our previous research in the field[37,60,72,78] and in our attempts to maximise the potential event rate and so minimise the required sample size, the pressure ulcer incidence rate of 25.2% was higher than predicted. This was achieved by the inclusion of patients with evidence of acute illness and at 'high risk', where 'high risk' defined as one or more of the following: bedfast/chairfast *and* completely immobile/very limited mobility;[51] localised skin pain on any pressure area skin site; and category 1 pressure ulcer on any pressure area skin site. The incidence rate is comparable to that in other reports of the incidence of category 2 and above pressure ulcers. In our systematic review of risk factor studies[46] (see *Chapter 5*), 19 studies reported incidence rates for grade/stage 2 and above pressure ulcers, ranging from 10.1% to 45.7% in heterogeneous patient populations. Of importance in terms of generalisability was our recruitment of community patients. The observed incidence rate in the community patient population was 26.3%, although it is noteworthy that the majority of 'community' patients were recruited from rehabilitation units, with only small numbers recruited in the home.

The age of our patient population was higher than expected from our previous prospective research,[40–43] with a median of 81 years and 31.2% of those recruited aged > 85 years. The age profile is, however, consistent with the community pressure ulcer prevalence population (median 81 years; see *Pain prevalence in hospital and community populations*, *Results*) and suggests that the population is representative of high-risk patients.

An unexpected finding was the high proportion of patients (77.1%) who reported pain at baseline. Although a number of these patients also had category 1 pressure ulcers, the extent of the problem was

underestimated in our sample size estimate (the sample size assumption was that 10% of patients would report pain at baseline). The sample size calculation assumed that at inception 15% of patients would have pain and that those would be an incidence rate of 10% in those patients with pain at baseline and 24.4% in those without pain. However, the incidence rate for those who reported pressure area pain on skin assessed clinically as normal, altered or category 1 was observed to be 28.0% and the incidence rate for those patients with no pain at baseline was observed to be 15.9%. Assuming an incidence of 28.0% for those with pain and 15.9% for those without pain, and that the proportion of patients with pain is equal to 77.1%, we would have required a reduced sample size of 535 patients to detect a difference between those with pain and those without pain at baseline with 80% power. Therefore, based on the data observed, we had an increase in power to 84% to detect a statistically significant difference in pressure ulcer incidence between those with pain and those without pain at baseline.

There was significant evidence that the presence of pain at a skin site is an independent predictor for developing a category 2 or above pressure ulcer, after adjusting for skin status (i.e. healthy, skin alterations, category 1 pressure ulcer) at baseline, across all four multivariable models.

At a patient level, the presence of pain on at least one skin site (healthy, altered or category 1 skin status) increased the odds of developing a category 2 or above pressure ulcer by 30 days of follow-up (primary end point) and also reduced the time to develop a category 2 or above ulcer compared with if pain is not present after adjusting for skin status.

At a skin-site level, the presence of pain is a predictor for developing a category 2 or above pressure ulcer on the same skin site by 30 days of follow-up, after adjusting for skin status and between-patient variation.

The other risk factors that emerged throughout the multivariable analyses included the presence of a category 1 pressure ulcer at baseline, consistent with all four previous studies,[37,60,79,80] which have included this as a variable in multivariable modelling. The presence of alterations to intact skin has also emerged in multivariable modelling in 9 of 10 studies where it has been included as a variable[46] (see *Chapter 5*, *Research overview*).

The study was designed to incorporate key quality criteria for the conduct and reporting of risk factor/prognostic factor studies[81–89] to promote generalisability and minimise bias. The study design, including an a priori sample size estimate and data monitoring, ensured that there was a sufficient number of events to undertake robust statistical modelling incorporating key risk factors determined through systematic review and the development of a conceptual framework. The primary outcome, the development of a new category 2 or above pressure ulcer, provides the most reliable outcome measure.[56] Clear inclusion and exclusion criteria were applied, screening logs were maintained to assess the generalisability of the study population and trained clinical research nurses undertook all baseline and follow-up assessments providing high-quality data and minimising loss to follow-up. Patients were recruited from both acute and community settings, which were representative of UK 'standard care'. All centres had pressure ulcer prevention and management policies and guidelines in place, including risk assessment, mattress provision, turning (and so on). The majority of patients received the recommended National Institute for Health and Care Excellence (NICE) standard mattress provision of either a high-specification foam mattress or an alternating pressure mattress[15] and members of the research team did not alter standard care provision as determined by the local ward/community teams, who remained responsible for clinical care.

The limitations of the study included a lack of blinded outcome assessment. This could have been achieved if baseline and follow-up assessments had been undertaken by two different research nurses; however, there was not the funding or capacity within the tissue viability teams for this approach. It is feasible that the research nurses could have introduced bias to the outcome assessment. The feasibility of using photography for independent blind outcome assessment is currently being determined as part of the HTA programme-funded PRESSURE 2 trial [for details see http://medhealth.leeds.ac.uk/info/423/skin/1717/pressure_2 (accessed 13 July 2015)].

It is acknowledged that the patient population is not representative of the general NHS population because of exclusion of patients who had cognition problems, patients who were very sick or terminally ill and patients who either were unable to provide consent or it was considered unethical to approach. However, as pain is a symptom of underlying inflammation and/or nerve damage we suggest that the results are generalisable to the wider population and that efforts to assess pain, soreness and discomfort are made for all patients using pain assessment methods established for this group of patients.[90–92]

It is also acknowledged that patients with darkly pigmented skin were under-represented in the study population. As indicated above, however, as pain is a symptom of underlying inflammation and/or nerve damage we suggest that the results are generalisable to the wider population.

Patient and public involvement in the pain workstream

As with all of the PURPOSE studies, high-level service user input has been present throughout via the steering committee. The majority of study-specific involvement has focused on interpreting and disseminating findings. The results of the pain studies were presented to PURSUN UK who reported that the work echoed many of its members' own experiences. PURSUN UK members felt that pain is an important and often overlooked area and as such it is important that the results of this study are disseminated to front-line health professionals. They gave the project team feedback from the service user perspective on questions that remained unanswered, for example the lack of clear pain management strategies for pressure ulcers and the difficulties of assessing pressure area pain in complex, at-risk patients.

Three PURSUN UK members with experience of pressure ulcer/pressure area pain have worked with the PPI officer to develop written vignettes about their experiences. These narratives aim to illustrate the importance of the pain studies and put the findings in a real-life context. The vignettes will be included in a forthcoming publication, co-authored by three members of PURSUN UK and aimed at clinical nurses.

Conclusion

A major advantage of prevalence surveys is that they provide a general estimate of the extent of a problem. The results of this study provide a very strong indication that pressure area-related pain affects a significant minority of patients without pressure ulcers in hospital populations and that a substantial proportion of patients with pressure ulcers report pain. Pain severity is not related to severity of the ulcer and both inflammatory and neuropathic pain are observed. We nested the pain prevalence studies within routine pressure ulcer prevalence audits and in the community setting the case-finding method used was not standard. We observed different prevalence rates in the two localities, highlighting the importance of clear methodological descriptions and effective case ascertainment for study comparison and in establishing the true prevalence of pressure ulcers in a community setting.

We have also established that the presence of pain (on skin areas assessed as healthy, altered but intact or category 1) increases the probability of category 2 and above pressure ulcer development and accelerates the time to ulcer development. This is an area of practice that requires improved assessment, incorporation into risk assessment and treatment strategies to alleviate pain and reduce category 2 pressure ulcer development.

Chapter 4 Severe pressure ulcer study

Chapter written by Justin Keen, Susanne Coleman, Carol Dealey, Elizabeth McGinnis, Delia Muir, E Andrea Nelson, Malcolm Patterson, Lisa Pinkney, Nikki Stubbs, Lyn Wilson and Jane Nixon.

Abstract

Introduction: There is good evidence that pressure ulcer risks are associated with patients' health status or their behaviour. There is also suggestive evidence that the organisation of treatment and care can influence patients' risks. The principle research objective of this work package was to understand the ways in which the organisational context influences the development of severe pressure ulcers. A second, practical objective was to identify ways in which root cause analyses of reportable pressure ulcers could be improved on, to maximise the chances of learning from them.

Methods: The severe pressure ulcer work package comprised three pieces of work: (1) a retrospective case study based on eight patients who developed severe pressure ulcers; (2) a patient involvement workshop with PURSUN UK; and (3) development of a methodology for root cause analyses of critical incidents.

Results: For seven of the eight patients in the retrospective case study the best explanation of the evidence was that the general organisational context played a significant role in severe pressure ulcer development. In four accounts specific events contributed to development. One patient's severe pressure ulcer was deemed to be unavoidable. Service users found the interactive workshop format, and the use of a 'simulated patient' account within it, valuable. A methodology for root cause analysis, rooted in current NHS practice but including novel components, can be used to improve the quality of the insights captured.

Conclusions: Severe pressure ulcers were more likely to develop in contexts characterised by one or more of clinicians failing to listen to patients or carers, clinicians failing to recognise and respond to clear signs that a patient had a pressure ulcer or was at risk of developing one, and services not being effectively co-ordinated. Presenting research data in live and interactive formats can make the interpretation process more engaging and accessible to service users and support meaningful dialogue between service users and professionals. Current best NHS practice in root cause analyses of reportable pressure ulcers should be augmented by interviews with patients and carers and by the construction of narratives based on key events. Our findings suggest that there is a need to move away from identification of *root causes* and towards broader *explanations* of events, based on identifying the 'best fit' between the available evidence and the explanations available in the patient safety literature.

Background

There are two distinct ways of thinking about patients' risks of developing pressure ulcers. The first is based on the assumption that all pressure ulcer risks are associated with patients' health status or their behaviour. Clinicians should therefore focus on identifying patients who are at risk, assess the nature and scale of their risks and design clinical interventions to reduce them.[46] This approach, which highlights the importance of risk assessment, informed our work on pain (see *Chapter 3*) and risk assessment (see *Chapter 5*). The second way of thinking starts from a different assumption, which is that the quality of treatment and care can also influence patients' risks of developing pressure ulcers. Some environments are riskier than others so that patients who are at risk are more likely to develop pressure ulcers in settings where there is poor-quality treatment and care. The events at Mid Staffordshire NHS Foundation Trust, where at one point dozens of pressure ulcers were being reported every month, help to underline the significance of this point.[93]

This study is rooted in the second way of thinking. It informs a number of Department of Health policies. For example, category 2 or above pressure ulcers, as rated on the EPUAP/NPUAP 1–4 scale,[1] are classed as reportable incidents in official guidelines.[94] Category 3 and 4 pressure ulcers have to be reported as serious untoward incidents. Pressure ulcers are one of four patient safety indicators in the NHS Safety Thermometer and there are incentive payments for avoiding pressure ulcers in the Commissioning for Quality and Innovation (CQUIN) framework.[95] The NHS has a 'no avoidable pressure ulcers' goal and, as a result, pressure ulcer prevention is classed as a high-impact action for nursing and midwifery.[96] Yet there is limited evidence about the ways in which care processes influence the development of pressure ulcers and severe pressure ulcers. This study therefore focuses on the ways in which care processes influence the development of pressure ulcers by reconstructing events leading to the development of severe pressure ulcers in eight patients.

Aims and objectives

To implement national policies and reduce the incidence of pressure ulcers, clinicians need to understand how and why their actions increase or decrease the likelihood that patients will develop them. Our principal research objective was, accordingly, to explain the influence of organisational context on the development of pressure ulcers. Beyond this, we stated in the programme proposal that we would investigate the implications of our findings for the conduct of root cause analyses. A second, practical objective was therefore to identify ways in which root cause analyses of reportable pressure ulcers could be improved on, to maximise the chances of learning from them.

Research overview

The severe pressure ulcer work package comprised three pieces of work. The first was an empirical study designed to improve our understanding of the ways in which care processes influence the development of severe pressure ulcers, in which we constructed detailed retrospective accounts of the development of severe pressure ulcers in eight patients. The second presents the design and conduct of a patient involvement workshop, drawing on one of the accounts from the empirical study. The third sets out the development of a methodology for root cause analyses of reportable pressure ulcers.

Retrospective study of the development of severe pressure ulcers

Aim

We undertook an empirical study designed to improve our understanding of the development of severe pressure ulcers by constructing detailed retrospective accounts of the development of severe pressure ulcers in eight patients.

Methods

Design

The research design was substantially influenced by two arguments. The first stemmed from discussions at the start of the study. Although our principal objective concerned the effect of organisational context on the development of severe pressure ulcers, we realised that we could not simply assume that a relationship between the two existed and could be studied empirically. Indeed, the available empirical evidence is limited, but the literature offers three distinct explanations,[97,98] namely:

1. pressure ulcers develop following a mistake made by an individual clinician[99,100]
2. they develop as a result of a sequence of otherwise unconnected mistakes[101–103]
3. there are systemic weaknesses in the organisation and delivery of care, such that the regime is one in which pressure ulcers are more likely to develop.[104–106]

We decided that it would be necessary to discriminate between these candidate explanations to establish whether, and how, the organisational context helped to explain the development of severe pressure ulcers or alternatively played no role. We should also include two other logical possibilities, in order to identify their role in explaining development or eliminate them from consideration, namely (1) the behaviour of clinicians had no effect on the development of a pressure ulcer, which would have developed whatever they had done, and (2) there was an alternative explanation, which had not previously been reported or hypothesised.

The second argument flowed from the nature of the domain that we were studying. Severe pressure ulcers occur relatively rarely and can develop in a wide range of settings over periods of days or weeks. It is not currently possible to predict who will develop them and who will not; it is only possible to identify people who have already developed a severe pressure ulcer. A prospective study was therefore not feasible. We opted to identify patients who had developed severe pressure ulcers and to reconstruct what had happened to them. This led us to adopt a retrospective case study design. A process-tracing case study method was used to capture the experiences of eight individuals who had developed severe pressure ulcers.[107] Accounts of their experiences were developed, which were then compared and contrasted to identify common features and hence common explanations. The two arguments taken together led us to develop a novel research design.

Setting

Eight patients were recruited in six NHS trusts in Yorkshire, England. Four patients' accounts occurred wholly or mainly in acute hospitals, three mainly in their own homes and one in a combination of a community hospital and an acute hospital rehabilitation ward. The decision to recruit eight patients was pragmatic: each account took approximately 4 months from initial interview to completion of analysis and we were therefore able to complete eight accounts with the resources available to this study.

Eligibility

Inclusion criteria

The study method was piloted with the first patient, who presented with few comorbidities, on the basis that the patient's problems would be less likely to be confounded with organisational factors.

Subsequent patients were recruited from participating acute and community trusts if they:

- had a current or previous category 3 or 4 pressure ulcer
- were a hospital inpatient, hospital outpatient, intermediate care patient or community patient under the care of community nursing services.

Recruitment was designed to maximise the variation and presentation of severe (category 3 and 4) pressure ulcers, including anatomical site (e.g. heel, sacrum, buttocks).

Exclusion criteria

Patients were excluded if:

- it was considered ethically inappropriate to approach them, for example those whose death was imminent
- they were unable to tell the story (narrative) of their experience.

Recruitment and consent

Participants were sampled partly to maximise the diversity of individuals and the contexts in which they developed severe pressure ulcers and partly purposively (see *Appendix 10*). Eligible patients were identified by members of the local tissue viability nurse teams at one of the six study sites in Yorkshire, England, who informed them about the study and provided them with a study information leaflet and an 'agree to be contacted by the researcher' form (see *Appendix 11*). Consent to participate was obtained from individuals and, when appropriate, also from their main carers (see *Appendix 12*).

Data collection

Data were collected by a field researcher (LP) with a non-clinical background from five sources, namely interviews with individuals who had developed a severe pressure ulcer (and, when relevant, their main carers), interviews with clinical and other staff who had been involved in their care, clinical records, other documents relevant to the account such as critical incident reports, and relevant local policy documents (e.g. on the conduct of skin risk assessments) (*Figure 10*, stage 1). A parallel review of patient notes was undertaken by a tissue viability nurse at each study site.

Patients were interviewed first and invited to give their account of the reasons why, in their view, their severe pressure ulcer had developed. Interviews were semistructured and lasted between 30 and 90 minutes. They were digitally recorded and transcribed.

The patient interview was used to direct the next phase of data collection, which involved accessing and reviewing nursing, medical and therapist notes, clinical incident reports and other documents (e.g. staff rotas for key periods of time in the patients' accounts). An initial analysis of the documents was undertaken and, on the basis of the analysis and the patient account, an initial interview schedule was drawn up. The analysis was also used to identify members of staff who were likely to be able to provide useful information about the development of the severe pressure ulcer. After the initial interviews, the researcher discussed the emerging possible explanations with the site tissue viability nurse specialist and a list of further interviewees was agreed. It is worth noting that, for this and subsequent analyses, the focus was on understanding how severe pressure ulcers developed, but a range of contextual information was provided in interviewees' responses and in the documentation provided that could be used to discriminate between the explanations identified earlier.

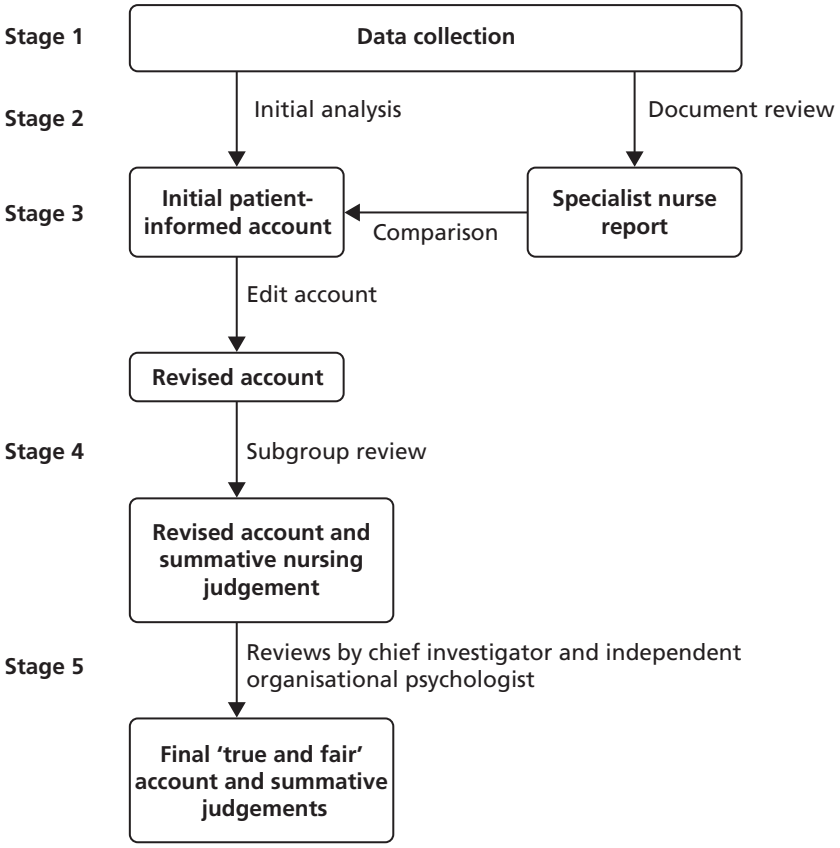

FIGURE 10 Analysis and review of individual accounts.

Interviewees for hospital-based accounts included matrons, ward nurses, health-care assistants, ward clerks, ward managers, physiotherapists and consultants. In community settings, interviewees included district nurses, home care assistants and therapists (*Table 25*). At least seven interviews were conducted for each account except for the eighth account, in which an individual developed a severe pressure ulcer in her own home after a fall and few health professionals had useful information about her circumstances. Few professionals were directly involved in identification of and response to her ulcer, and comprehensive notes were available about her assessment and treatment only once she came into contact with health services. In total, 70 interviews were conducted across the eight accounts. Judgements were made about the time period that each account needed to cover and the extent of the documentation that was needed. In some instances, both were extended when it became clear that the histories were longer or more complicated than at first appeared.

Analysis

Transcripts of patients' interviews were reviewed and key passages that set out their accounts of events were included verbatim at the start of each account. This was done partly because the patient (and in some cases also the carer) was the only person who had been present throughout and partly to guard against losing sight of the 'patient's voice' in subsequent analysis. A Microsoft Access® 2010 database (Microsoft Corporation, Redmond, WA, USA) was then created for each account and used to organise key decisions and actions into a chronological sequence. Patient- and carer-derived data were recorded in one column, clinician interview data in a second and clinical record and other documentary sources in a third (see *Figure 10*, stage 2). The presentation of data in parallel columns made it possible to develop a chronological account of events, identify consistencies and inconsistencies between different data sources and assess the 'strength' of evidence available about key events, reflected in the number and quality of sources. These data were used as the basis of a single, provisional timeline of events.

The site principal investigator, who in each case was a nurse with a specialist interest in tissue viability, undertook a parallel review, based solely on available patient records and on other available documentation, including local guidelines and critical incident reports. The review followed the guidance for reviews of critical incidents in the NHS.[94] The investigator wrote a report, identifying key decisions and actions in chronological order, including departures from local guidelines. The field researcher and site principal investigator then met and compared their accounts, identifying consistencies and inconsistencies (e.g. actions that the nurse judged as important that were not included in the researcher's account). The timeline in each initial account was revised in light of additional facts or insights generated (see *Figure 10*, stage 3).

Refinement of the accounts

The initial summaries of each account, supported by transcripts of all of the interviews conducted, were reviewed by a subgroup of nursing members of the research team, one independent hospital-based and one independent community-based tissue viability nurse specialist and one of the co-chief investigators (JN) (see *Figure 10*, stage 4). The subgroups met and reviewed the summaries and transcripts, identifying points where, in their professional opinion, there was a departure from 'good usual care' (e.g. category 2 pressure ulcer was recorded in the nursing notes but no additional action to treat the ulcer or prevent deterioration was reported). The meetings were recorded and transcribed.

The subgroups were asked to make summative judgements about the best explanation for the development of a severe pressure ulcer for each account. The method for this stage of the study drew on Yin's[108] strategy for eliminating hypotheses in case study research. The subgroups were invited to select one or more of the following five explanations for the development of a severe pressure ulcer:

1. it could not have been avoided
2. there was a single precipitating event
3. there was a sequence of precipitating events
4. the organisational context made development more likely
5. there was another explanation, not covered by the first four.

TABLE 25 Numbers of people interviewed by account

Account	Individual	Carer	TVN	District nurse	Staff nurse	HCA	Consultant	Junior doctor	Physiotherapist	Occupational therapist	Ward clerk	Liaison nurse	Ward manager	Quality assurance manager	Total
1	1	1	2		2	2	1		1	1	1	1	1		14
2	1		1		2	3	1	1	1		1		1		12
3	1		1		2		1		1					1	7
4	1	1	1	1	1	1			1						7
5	1	1	2	2	3	1							1	1	12
6	1		1		2	1	1						1		7
7	1	1	1	1	2	2									8
8	1	1	1												3

HCA, health-care assistant; TVN, tissue viability nurse.

The second, third and fourth explanations were derived pragmatically from the literature on patient safety, with each representing a major class of explanation for adverse events.[109,110] The other two – the first and fifth explanations – were logical alternatives to the first three (i.e. the organisation of care played no role and there was an explanation that was not predicted by any of the three theories). We did not define key terms such as 'precipitating event' and 'organisational context' on the basis that subgroup members were expected to articulate the reasons why they opted for different explanations and in so doing would provide their own definitions in each account.

Viewed in the context of patient safety studies, this approach is novel, taking the study away from a narrow focus on root causes (i.e. only allowing causal explanations of events to be considered) and towards the broader classes of explanations in the safety literature. There is a technical point here, which is that the explanations are not based on causal relationships but on identifying the 'best fit' between the available data and one of the explanations.

The discussion leading up to the summative judgements, and the judgements themselves, were included in the revised accounts. The accounts at this stage therefore had three discrete sections, namely the patient's account, the interpreted timeline and nurses' summative judgement. The subgroups sometimes made queries about details of the accounts. After each meeting the queries were checked by going back to primary data sources and accounts were amended as appropriate.

The last two stages of the analysis were reviews of the individual accounts by a non-clinical co-chief investigator (JK) and then by an organisational psychologist (MP) who had not been involved in the earlier stages (see *Figure 10*, stage 5). The reviews focused on the coherence of each account (i.e. the extent to which the patient's explanation and/or the nurses' judgements made sense of the available evidence).

In the final step in the analysis, the accounts were compared with one another to identify themes that were common across the accounts, even though the details of the individuals, their pressure ulcers and the care settings varied widely. The themes were analysed inductively to develop a mid-range theory of the reasons why patients develop severe pressure ulcers.[109]

Results

The study demonstrates that it is possible to develop detailed retrospective accounts of events and to use them to judge which of five possible explanations best fits the available evidence. The large volumes of data collected and included in the timeline appear to have minimised problems that might have arisen as a result of 'missing data'. However, as we note in the discussion, the results may still be subject to a number of biases.

The eight accounts

The eight patients were selected, in part, to maximise diversity (*Table 26*). Unsurprisingly, then, there were marked differences in the details of their treatment and care and different explanations were offered by those interviewed for the development of severe pressure ulcers.

Seven of the eight – the exception being number 8 – exhibited widely recognised risk factors and had complex treatment and care needs. In a number of accounts some staff who were interviewed blamed the patients, on the basis that they had not complied with advice on managing their risks (e.g. shifting position regularly). But patients themselves, in the same accounts, generally pointed to specific actions or omissions, such as the failure to be turned regularly overnight, to be provided with a specialised mattress or to act on patients' comments about their own risks.

Participants approached interviews in very different ways. Some patients and carers were very clear in their own minds about what had gone wrong whereas others were very reluctant to criticise any aspect of their care. Similarly, some accounts involved individuals moving between wards, or an account developed against a background of a major ward reorganisation. The significance attributed to these moves varied, including, for example, the failure to transfer notes with patients, which placed receiving staff at a disadvantage, and staff feeling harassed because they were working in an unfamiliar environment during a reorganisation.

TABLE 26 Individuals and settings

Account	Individual	Setting
1	38-year-old woman with paraplegia	Acute hospital, surgical ward
2	65-year-old woman with a long-term chronic neurological condition and undiagnosed infection	Acute hospital, medical ward
3	75-year-old man with multiple chronic health problems and acute infection	Community hospital, rehabilitation ward
4	37-year-old woman with a long-term degenerative congenital neurological condition	At home
5	90-year-old man with multiple chronic health problems and undiagnosed acute illness	Acute hospital, surgical ward
6	39-year-old woman in hospital for acute undiagnosed postoperative surgical complications	Acute hospital, surgical ward
7	65-year-old man with quadriplegia	At home, respite care and acute hospital
8	89-year-old woman who fell at home	At home

Elimination of hypotheses

The diverse group of individuals all had the same outcome: a severe pressure ulcer. In one account (number 8), the review teams judged that the development of the pressure ulcer was unavoidable, because the individual concerned developed a severe pressure ulcer in her own home, before any health professional saw her. In another account (number 3) there was a single precipitating event and in three other accounts (numbers 2, 4 and 6) there was a sequence of events. But the clinical subgroup and subsequent reviewers all judged that the organisational context made development more likely in seven of the eight accounts (*Table 27*). It is possible that the organisational context made the 'key events' in accounts 2–4 and 6 more likely, although we cannot make causal inferences with any confidence on the basis of our evidence. The evidence suggests that the term 'organisational context' covers two distinct concepts. The first concerns the prevailing cultures in the settings where severe pressure ulcers developed (see *Cross-patient themes*). The second relates to what one might term the functional characteristics of those settings, particularly nursing staff shortages, staff who (justifiably or not) did not believe that they had enough time for proper treatment and care and wider organisational issues, including contemporaneous reconfigurations of services in four of the accounts.

TABLE 27 Summative judgements by account

Account	Unavoidable	Single/isolated event	Sequence of events	Environment made development more likely	Other explanation
1				✓	
2			✓	✓	
3		✓		✓	
4			✓	✓	
5				✓	
6			✓	✓	
7				✓	
8	✓				

Cross-patient themes

The process of eliminating hypotheses, and the analysis of common themes across the eight individuals, led to the identification of three broad themes. First, the 'voices' of those who developed severe pressure ulcers, and of their carers when they were involved, were not heard by staff. As noted earlier, the individuals themselves behaved differently and had different relationships with clinical staff, but failures to heed information were evident in several accounts. There were examples of patients making repeated appeals for pain and discomfort to be addressed and expressing concerns about their own well-being that were not heeded over periods of hours or even days. In some instances, these appeals seem to have been dismissed by staff, that is, they were heard but were not taken seriously. Patients were also blamed for the development of their pressure ulcers on the basis that they did not comply with instructions that they were given, and were branded as 'difficult', even when they had a cognitive impairment.

Second, there were failures to recognise and act on warning signs. Risk assessments were not undertaken when they should have been and, in some cases, they were undertaken only several days after admission to an acute hospital ward. Evidence of pre-existing clinical risks in records was not acted on in six of the seven cases in which the environment was judged to have made development more likely. Action was not taken promptly when overt evidence, including the presence of a category 2 pressure ulcer, was identified. In interviews, there were a number of instances of staff blaming colleagues for these failures. Conversely, there was evidence of poor documentation, so that adherence with patients' care plans was not recorded and, in some instances, direct evidence of skin redness or a pressure ulcer was not recorded. Some health-care assistants, who provided direct care, observed that they lacked the appropriate training to identify and record risks or were not allowed to record them.

Third, there were co-ordination failures, between patients, carers and staff, between staff in the same setting, between staff in different settings in the same organisation (e.g. two wards) and between staff in different organisations. Sometimes this was manifested as interprofessional communication failure and sometimes there was poor communication between the same professional groups in two locations. One example of the latter came in a postoperative setting where risks were not properly communicated between the anaesthetic recovery unit and the postoperative ward. In other accounts, records were not moved with an individual so that key information was not available in a new setting. Again, in staff interviews these problems were often recognised but in contexts in which interviewees were defensive, tending to blame others rather than taking responsibility for their individual or collective actions.

It would be possible to interpret these co-ordination failures as clear evidence of failure by individuals or teams. But there is a corollary to this point: nurses and health-care assistants, in particular, could find themselves working in conditions in which they had limited information about individuals and their risks (e.g. patients had an unknown diagnosis) or in which records had not travelled with a patient from another location. It is possible, therefore, that individual members of staff behaved reasonably in the contexts in which they found themselves; the problems lay more with the overall co-ordination of treatment and care.

The larger and broader finding – the mid-range theory arising from the findings – is that individuals developed severe pressure ulcers in environments where there were problems with the prevailing culture. This cultural explanation binds together the otherwise separate points made above. In most accounts there was a combination of problems – some staff blaming colleagues or describing patients as 'difficult', poor documentation and failures to act on repeated clear warning signs (i.e. to step up care provision when a superficial pressure ulcer was observed), so that a severe pressure ulcer was 'allowed' to develop. In these contexts responsibilities were not clear and staff interviews pointed to problems with team working, extending beyond the specific accounts that we were producing.

Discussion

This study sought to improve our understanding of the ways in which the organisational context contributes to the development of severe pressure ulcers and in doing so to discriminate between alternative explanations for their development in the research literature. The principal explanation is that severe pressure ulcers are more likely to develop in particular organisational contexts. The contexts were characterised by one or more of (1) clinicians failing to listen to patients' or carers' observations about their risks or the quality of their treatment and care, (2) clinicians failing to recognise and respond to clear signs that a patient had a pressure ulcer or was at risk of developing one and (3) services not being effectively co-ordinated. These can all be interpreted as failures in the governance of the services in the settings studied.

As noted in the methods section the study was designed in significant part to minimise biases in data collection and analysis. The study suggests that a novel method, based on tracing back the course of events retrospectively from a known outcome, can be used to reconstruct key events. The resulting accounts can be subjected to detailed review and used to discriminate between alternative explanations for those events, in the process preserving the 'voices' of the individuals affected. That said, it is important to stress that there are a number of sources of bias, starting with selection bias: although the sampling strategy maximised diversity, the eight accounts are of individuals who were willing and able to consent to participate. The initial presentation of the timelines and the backgrounds of the analysts and reviewers are also potential sources of bias. A study team with a different clinical or disciplinary background might have arrived at different judgements, for example a team with a background in human factors psychology might have placed greater weight on single events or sequences of events. Using a retrospective design, there is also a risk of hindsight bias, particularly in terms of reviewers assuming that staff must have known more than they actually did and should therefore have acted differently.[110] The sequential and iterative review process has, we hope, served to minimise these biases but we cannot say that they have been eliminated.

We can place our findings in the context of the patient safety literature. Reason[111] points out that investigations of accidents, across many industries, have changed significantly over the last 50 years. An early focus on equipment failure gave way, in the 1970s and 1980s, to a focus on human error and then more recently to accounts that focused on systems and cultural issues. In spite of this, many patient safety studies today focus on explanations based on narrowly defined human factors and relatively few focus on the wider organisational context.[112] The findings reported here do not support the kinds of explanation that might have been advanced in the first two periods or by researchers focusing on human factors in clinical decision-making today. They are, though, consistent with explanations that emphasise systems and culture. This point is worth emphasising: our findings suggest that there is a need to move away from identification of *root causes* and towards broader *explanations* of events, based on identifying the 'best fit' between the available evidence and the explanations available in the patient safety literature.

As we noted earlier, explanations tend to emphasise either systems-based or cultural explanations. The results of this study suggest that, for people who developed severe pressure ulcers, both were important. In relation to systems-based explanations, the evidence about the poor co-ordination of services is broadly consistent with the Institute of Medicine's arguments in *To Err Is Human*, namely that many safety failures are essentially system failures.[113] Drawing on the work of Perrow[110] and others, the Institute argued that accidents are more likely in systems that are inherently complex – having many interconnected elements. The findings in this study support the observation that there were co-ordination failures between services that were loosely coupled with one another (i.e. that are managed independently but need to co-ordinate with one another). For example, there were communication failures between wards at times when there were major ward reorganisations, so that key information was not passed on. Similarly, one of the community-based accounts revealed that the individual was in receipt of a hospital service that community staff were unaware of and hence could not take into account in risk assessment or care planning.

The findings cannot be wholly explained as co-ordination failures. The failure to listen properly to patients – and even dismissing their concerns – and to act when there was a superficial pressure ulcer present emphasises the importance of prevailing cultural norms. The evidence suggests that the environments where severe pressure ulcers developed were ones where staff were under time pressure, where there were problematic relationships between staff groups and where staff were defensive and prepared to attribute failures to colleagues or to the 'difficult' behaviour of patients. Clinicians adopted risky work routines that were not appropriate for the vulnerable patients who were in their care. Severe pressure ulcers developed in contexts in which risky practices had become the norm – in which there was normalisation of deviance.[114] This resonates with wider concerns about the culture in parts of the NHS in England, where staff have been defensive and quick to blame others.[46] The implication is that the effective prevention of severe pressure ulcers requires staff to adopt appropriate behavioural norms, including effective communication with patients, a commitment to the thorough assessment of risks and prompt action when things go wrong.

Finally, we have noted that there were often discrepancies between patient accounts, staff interviews and records. No one source provided all of the key information needed to understand what had happened and, as noted, accounts could conflict with another. This provides a clue about a potentially important weakness of existing root cause analysis processes. At present, NHS guidance recommends reviews of clinical records and interviews with staff but not interviews with patients and carers, without whose testimony some of the accounts would have been incomplete and might well have been interpreted wrongly, leading to the wrong conclusions and hence the wrong remedial interventions.

Patient and public involvement

In *Chapter 2* we described the creation of PURSUN UK. Members of PURSUN UK were invited to contribute to the interpretation of some of the findings from the retrospective study (see *Retrospective study of the development of severe pressure ulcers*). As we noted there, the evidence and interpretations provided by patients who had developed severe pressure ulcers proved to be important in the analysis. Patients and their carers were the only people who were present throughout; clinicians could be aware only of parts of each account. There was, though, a risk that the analysis, in ensuring that the accounts were accurate and coherent from a nursing perspective, might lose sight of patients' and carers' viewpoints. We therefore wanted to establish whether or not our accounts were 'true and fair' as perceived by patients with experience of having pressure ulcers.

Patients have only rarely been directly involved in the *interpretation* of research evidence, as opposed to being sources of evidence, in health services research.[115] A recent review of the literature on PPI found that involvement activities tended to focus on the early stages of research, such as identifying research priorities and aspects of study design. Only six studies were identified as having significant PPI in analysis or interpretation.[26]

Aim and objectives

To design and conduct a patient involvement workshop, drawing on one of the accounts from the empirical study. The workshop had two distinct purposes:

1. to assess the face validity of the account from the point of view of a group of service users
2. to disseminate the findings of the project to those service users.

Methods

Design: Pressure Ulcer Research Service User Network UK workshop model

We organised a workshop that was developed and facilitated by the PURPOSE PPI officer, the severe pressure ulcer study field researcher and one member of PURSUN UK. The workshop was designed along the broad lines of a public enquiry – albeit a benign one – in which participants would be invited to act as 'expert witnesses' in a case that was presented to them.

Three types of material were prepared before the workshop. First, one patient's account of her health problem and treatment was used to create a brief for a simulated patient. The PURSUN UK member with specialist expertise in health-related role play took on the role of the patient from the case. The researcher conducting the inquiry then interviewed the simulated patient about their experiences. This was presented live at the workshop. Various simulated patient models have been used in the UK since the late 1970s, typically in communication skills training or assessment for health professionals.[32] The approach was adapted here for use in a research context. Second, professionals' accounts of events were filmed and edited into short videos. Here, actors were given a brief, prepared by the workshop facilitators, and asked to improvise a piece to camera (they did not read from a transcript, in part to avoid using verbatim quotes, which might have led to the patient being identified). Third, a visual timeline of events was presented using Prezi software (Prezi, Budapest).

The workshop was held on 17 May 2012 in Leeds. It was attended by nine members of PURSUN UK, six members of the research project team and two NHS PPI managers.

Workshop evaluation

The workshop was, as far as we were aware, innovative and we were unsure how successful it would be. We therefore decided to evaluate it. Five participants took part in videoed interviews and one further audio-recorded interview was carried out by the PURPOSE PPI officer. The interviews took place both during the workshop, to provide immediate reactions, and afterwards, giving participants time to reflect before commenting. Three participants also chose to provide written feedback. Themes from the interviews and written feedback were then collated by the PURPOSE PPI officer. Participants were also offered the opportunity to provide anonymous feedback through a neutral third party but in the event this option was not used. Clips from the videoed interviews are available at http://youtu.be/bgg6zkbILrg (accessed 24 February 2015).

Results

The workshop model

Participants found the metaphor of a public enquiry useful as it helped to convey the design of the field study and the rationale for the 'expert witness' roles in the workshop. Participants found the simulated patient interview engaging and valued the interactive nature of the session. One member of PURSUN UK commented that she would not have become involved in the project if it had required her to take part in a complex, paper-based exercise. The live interview also provided a snapshot into a part of the research process that few had previously experienced. As the simulated patient stayed 'in role' during discussions, workshop participants were able to briefly step into the shoes of the interviewer, asking follow-up questions and checking assumptions.

Impact on workshop participants

Service users reported an increased understanding of research processes in general as a result of the workshop. Some members also said that it had made them think more about their own and their family's health, particularly in relation to preventing pressure ulcers. Some service users also reported an increased feeling of empathy for the health professionals dealing with such complex cases.

Members of the project team valued the dialogue with service users in a non-clinical context, despite some initial concerns about working in this way. Everyone felt that the collaborative nature of the workshop was important, particularly the fact that academics and nurses got to hear service users' opinions first hand.

Face validity

The workshop also provided us with feedback – admittedly for just one of the eight accounts – about the validity of the account. Members of PURSUN UK arrived at a similar interpretation of events as the nurses and other experts involved in the formal analysis reported in *Retrospective study of the development of severe pressure ulcers*.

The research team had already identified a need to involve patients and carers in the critical review of severe pressure ulcers in the NHS (see *Implementation project: the review of critical incidents*). This was supported by PURSUN UK members and one member has worked with the study team during 2013. PURSUN UK also highlighted the importance of patient/carer engagement in pressure ulcer prevention and the role that professionals can play in facilitating that engagement. Conversely, we recognise that the severe pressure ulcer case study findings were filtered through the materials prepared for the workshop. This was necessary partly to make the findings accessible and partly to protect the anonymity of the individual whose account was used.

Conclusions

Thinking carefully about how PPI activities are designed and facilitated is important as the format affects people's ability and willingness to contribute. Presenting research data in live and interactive formats can make the interpretation process more engaging and accessible and support meaningful dialogue between service users and professionals. The use of applied performance techniques, as described here, provides one model for doing this.

Implementation project: the review of critical incidents

The programme grant proposal included a commitment to investigate the implications of the study findings for the conduct of root cause analyses of occurrences of severe pressure ulcers.

Aim and objective

The aim was to develop a methodology that can be used to review reportable pressure ulcers in the NHS in England. The objective was to develop and test a method for reviewing severe pressure ulcers that incorporated two key features, namely consideration of organisational explanations for their development and eliciting information from patients. The first feature was derived from the main study and the second was an extension of the PPI study.

Overview of methods

The work was undertaken by two of the clinical experts who had been involved in the empirical study, the PURPOSE PPI officer, the programme chief investigator and the severe pressure ulcer study lead. A further member was co-opted who had a dual role, as a member of PURSUN UK, having recently experienced a severe pressure ulcer, and as a senior analytical researcher in a NHS organisation. An expert in adult safeguarding was also consulted in the course of the project.

The scope of the project was defined as follows: to devise an investigation process and template suitable for use in the NHS; to pilot this in both acute and community care settings; and to establish the added value of including the patient's voice and any differences in findings compared with the traditional root cause analysis process and the value of the findings for meaningful action planning and process changes. The methodology should also encourage open contributions, to learn what could be done better in future, learn what good practice we could disseminate and gain feedback on prevention and management interventions.

Based on the findings of the empirical study, the team took the view that the review methodology should include:

- a narrative of events associated with the development of a pressure ulcer, captured in conversations with patients and/or relatives/carers and with staff with knowledge of relevant events
- a timeline of events based on information from patient records
- identification of good practice – practices that patients might reasonably have expected
- insights from the empirical study (e.g. about the systemic nature of organisational risks)
- coverage of resource issues, to take into account current NHS resource constraints.

Initially, the team reviewed investigation methods currently used in the NHS, including the Herringbone and 5 Whys? methods,[116] both of which were endorsed by the National Patient Safety Agency before it was closed down. Strengths and weaknesses of current NHS root cause analysis practices have been described by Nicolini and colleagues[117] and their findings were used to inform our process.

We devised a method to direct data collection and the construction of patient narratives as follows: each scene was presented in terms of 'actions' taken by the actors, 'constraints' imposed on them, the 'information' they held and/or passed on and the 'decisions' they reached. This was initially tested informally using the patient member's own experience. The process can be summarised as:

- *beginning*, which covers setting up the study team, establishing the narrative or story of what happened from the patient notes and identifying the people who can contribute to the study
- *gathering*, which involves the conversations with staff, patients and carers and reviewing the narrative in the light of their contributions
- *analysing*, which is the process of sense making of the information gathered, looking at risks, good usual care and the constraints on the incident
- *reporting*, which draws the analysis together into findings and actions.

The two clinical team members consulted with their host organisations and obtained agreement to pilot the method. In preparation, a workshop took place with the tissue viability link nurses during their training day. The nurses were given information from the records of a member of PURSUN UK relating to the development of a severe pressure ulcer. They were asked to use a draft template to produce a timeline of events. In parallel, a conversation then took place between an investigator and the member of PURSUN UK, during which he described his account of events. The nurses at the workshop then considered the differences between the two accounts and reflected on the experience of involving a patient in the process. Some practical issues were raised, including what to do if the patient was unable or unwilling to contribute (or there were no relatives available) and whether or not the process would increase the chances of litigation. Overall, though, the nurses felt that including the patient's account added information that they would not otherwise have obtained and added value to the review process. Reviewing the event, it was noted that the systemic issues that were central to the empirical study were not identified by the nurses at the workshop. We judged that it would be necessary to provide prompts in any guidance for investigators, to encourage them to focus on systemic explanations for the development of pressure ulcers.

The template for recording events and the guidance for the investigator were revised in the light of the workshop. The two clinical team members then identified two patients and their carers within their own organisations who were willing to take part in a further pilot review process. Conversations took place and information was collected from patient records. The usual NHS root cause analysis process was carried out concurrently and separately. Data that might identify any individuals involved were removed prior to sharing with the project team. Details of time resources were considered and findings were compared with those of the usual root cause analysis process.

Results

Findings and reflections

The substantive findings of the reviews were consistent with those from the retrospective study (*Table 28*). Both reviews using the new method identified additional contributing decisions and actions, over and above those identified in the parallel root cause analyses. The patients and carers did not identify the key decisions and actions themselves; their descriptions allowed the investigators to do so. In both cases the patients and carers valued the opportunity to 'tell their own story'.

Feedback from ward staff

A meeting was held with the staff from the ward where the hospital pressure ulcer incident had taken place. This was to feed back the findings of the pilot investigation and to evaluate the process by eliciting staff views. Generally, staff thought that the process was more thorough than the current root cause analysis process and was more informative about the reasons why the pressure ulcer developed. They felt that the patient's account not only told them a lot about the development of the pressure ulcer but also gave them important feedback about other aspects of care. There were observations in the patient's account that they could not have obtained from any other source (e.g. an existing sore on the ankle). Some staff felt that it made 'uncomfortable reading' but that it was to be expected when a category 3 pressure ulcer had occurred. They agreed that it was no more uncomfortable than the current process. They acknowledged the value of more staff involvement in the process as people may take more note of the outcome of an investigation if they are part of the process. They also noted that nurses are currently carrying out root cause analysis without any training. Finally, the idea that an independent person should lead the investigation (i.e. not someone working on that ward) was supported.

TABLE 28 Summary of findings

Incident	Root cause analysis findings	New investigation framework findings
Community pressure ulcer incident	• No risk assessment • Poor documentation • Carers should have reported skin deterioration to district nurses sooner	• Organisational issues (multiple care providers but no lead or sufficient communication) • No one managing risk of pressure ulcers • Relative was not listened to by staff (felt she was being a nuisance) • Impact of shingles (further reduced mobility) on pressure ulcer risk was not recognised
Hospital pressure ulcer incident	• Delay in referral to dietitian for weight loss • Braden score did not suggest risk • Patients low mood made him reluctant to participate in his care • The site where the pressure ulcer developed was not listed on the skin checklist and was therefore not checked	• Organisational issues (no communication of risk or skin status between health-care professionals, staff prioritising preventing 'falls' rather than pressure ulcers, ignoring mattresses alarming) • Risk was not reassessed/identified when condition deteriorated because of pneumonia • Impact of pneumonia (was too ill to move himself) on mobility was not recognised • Reasons for patient 'refusing to move' were not explored

Conclusions

Our conclusions, based on the pilot work, are that:

- There is value in involving patients and carers in root cause analysis – they can provide important information that is not recorded in notes or reported by staff.
- A narrative approach also has value. Underpinning this point, we note that nurses at the workshop and review events instinctively focused on root causes, that is, on cause–effect relationships, such as failure to turn a patient frequently enough. The findings of the empirical study and of this implementation study suggest that, rather than focus on root causes, teams and independent investigators should be encouraged to consider systemic explanations, that is, they should consider different ways of interpreting the available evidence, ranging from 'one-off' errors by staff to wider cultural issues that need to be addressed.
- Root cause analyses should be co-ordinated by someone who is independent of the setting in which incidents occur and who has clinical knowledge that provides credibility and the capacity to help local teams to identify lessons that can be learned.

Summary

The severe pressure ulcer work package comprised three pieces of work. The first was a retrospective case study of eight patients who developed severe pressure ulcers. The second was a patient involvement workshop with PURSUN UK. The third focused on the development of a methodology for the root cause analysis of critical incidents.

The main field study set out to understand the ways in which the organisational context influences the development of severe pressure ulcers. For seven of the eight patients the best explanation of the evidence was that the general organisational context played a significant role in severe pressure ulcer development. In four accounts specific events contributed to development. One patient's severe pressure ulcer was deemed to be unavoidable. We found that severe pressure ulcers were more likely to develop in contexts characterised by one or more of clinicians failing to listen to patients or carers, clinicians failing to recognise and respond to clear signs that a patient had a pressure ulcer or was at risk of developing one, and services not being effectively co-ordinated.

The patient involvement workshop was an additional study that was not described in the programme grant proposal. Service users found the interactive workshop format, and the use of a 'simulated patient' account within it, valuable. We found that presenting research data in live and interactive formats can make the interpretation process more engaging and accessible to service users and can support meaningful dialogue between service users and professionals.

We also found that a methodology for root cause analysis, rooted in current NHS practice but including novel components, can be used to improve the quality of the insights captured. On the basis of our three pieces of work, we conclude that current best NHS practice in root cause analysis of reportable pressure ulcers should be augmented by interviews with patients and carers and by the construction of narratives based on key events. Our findings suggest that there is a need to move away from identification of *root causes* and towards broader *explanations* of events, based on identifying the 'best fit' between the available evidence and the explanations available in the patient safety literature.

In conclusion, this study has not led us to a model or template that can be used for the analysis of the development of severe pressure ulcers or other incidents. Rather, it reinforces the view, articulated by Francis[93] and others,[97] that reviews are more likely to be effective if (1) they pay closer attention to details of the functional, or systems-based, components and also (2) they are used in ways that promote learning rather than blame. We have pointed in this chapter, and in the development of a risk assessment tool (see *Chapter 5*), to the importance of collecting the right information and collating and presenting it systematically. This is only worthwhile if clinical teams working in settings where severe pressure ulcers develop reflect on, and work on, their local cultures. No tool yet invented will substitute for this internal reflection and commitment to change practice.

Chapter 5 Risk assessment

Chapter written by Susanne Coleman, E Andrea Nelson, Isabelle L Smith, Sarah Brown, Julia M Brown, Lyn Wilson, Delia Muir, Justin Keen, Carol Dealey, Elizabeth McGinnis, Nikki Stubbs and Jane Nixon.

Abstract

Introduction: Increasing evidence makes it timely to reconsider which risk factors should be considered in pressure ulcer risk assessment and how to prompt an escalation of interventions for secondary prevention and treatment. The primary aim of the risk assessment work package of the programme was to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of a Risk Assessment Framework for use in clinical practice. The work package consisted of five phases incorporating a systematic review, a consensus study, conceptual framework development, design and pre-testing of the framework and clinical evaluation of the framework.

Methods: (1) A systematic review of primary research to identify pressure ulcer risk factors; (2) a consensus study using a modified nominal group technique based on the RAND/UCLA (Research and Development, University of California in Los Angeles) appropriateness method, incorporating an expert group, review of the pressure ulcer evidence and the views of PURSUN UK to agree a draft pressure ulcer risk factor Minimum Data Set and develop a Risk Assessment Framework; (3) development of a pressure ulcer conceptual framework and theoretical causal pathway, building on the phase 2 consensus study; (4) design and pre-testing of the draft Risk Assessment Framework using cognitive pre-testing methods, to assess and improve its acceptability and usability with clinical nurses; and (5) clinical evaluation of the reliability, validity, data completeness and clinical usability of the Risk Assessment Framework through field testing of 230 patients by expert and community/ward-based nurses.

Results: (1) The systematic review of primary research identified 15 risk factor domains and 46 related subdomains. The review indicated that there were three primary risk factor domains of mobility/activity, skin/pressure ulcer status and perfusion (including diabetes), but suggested that no single factor can explain pressure ulcer development. Other risk factor domains emerged less consistently. (2) The consensus study facilitated the agreement of risk factors and assessment items for the Minimum Data Set (including immobility, pressure ulcer and skin status, perfusion, diabetes, skin moisture, sensory perception and nutrition), allowing the development of a draft Risk Assessment Framework incorporating all Minimum Data Set items. (3) The new pressure ulcer conceptual framework incorporated five key components (mechanical boundary conditions, physiology and repair, mechanical properties of the tissue, geometry of the tissue/bone, and transport and thermal properties) and their impact on internal strains, stresses and damage thresholds. The theoretical causal pathway for pressure ulcer development identified direct causal factors, key indirect causal factors and other potential indirect causal factors for pressure ulcer development. (4) The design and pre-testing of the Risk Assessment Framework led to improved usability over the course of the three pre-test sessions, as demonstrated by increased data completeness and appropriate pathway allocation. (5) The field test demonstrated that inter-rater and test–retest agreement for the PURPOSE-T was 'very good' for the assessment decision overall as determined by kappa. The percentage agreement for the assessment of 'problem/no problem' for the eight risk factors (mobility, skin, previous pressure ulcer, sensory perception, perfusion, nutrition, moisture and diabetes) ranged from 79.1% to 94.2% for inter-rater reliability and from 87.0% to 93.9% for test–retest reliability. Convergent validity, assessed by comparison with the same or similar constructs on other risk assessment scales (Braden and Waterlow), demonstrated moderate to high associations. In addition, field notes recorded by the expert nurses highlighted positive and problem aspects of using the tool in the clinical environment. A follow-up consensus process allowed consideration of evidence from the pain work package and an extension of the pressure ulcer and skin status assessment items to include pressure area-related pain at the full assessment stage of the PURPOSE-T.

Conclusion: The work package led to the development of a new Risk Assessment Framework, the PURPOSE-T, incorporating the Minimum Data Set; a screening stage to target assessment towards those in need; a full assessment stage; use of colour (rather than a score) to describe risk in terms of a personal profile to help in the planning of appropriate interventions; and decision pathways that make a clear distinction between patients with an existing pressure ulcer(s) (or scarring from previous ulcers) who require secondary prevention and treatment and those at risk who require primary prevention. The final PURPOSE-T framework has content, face and construct validity, with good inter-rater reliability and very good test–retest reliability.

Background

It is not appropriate to prevent pressure ulcers by subjecting all patients to resource-intensive interventions (such as repositioning by nurses or expensive mattresses) that may impact on their quality of life (e.g. by disturbing sleep) and cause harm by diverting nursing time from other areas, hence we must target care to those patients for whom it is likely to do more good than harm. Targeting patients for whom pressure ulcer prevention interventions are needed is achieved by considering the patients' characteristics, a process known as risk assesssment. It is noteworthy that this is an individualistic approach to determining if someone is likely to develop a pressure ulcer, in contrast to the interaction/context-based explanantions identified as also being important in our study of severe pressure ulcers (see *Chapter 4*). Regardless of context, risk assessment is widely accepted as being essential for pressure ulcer prevention[1,14,23] as it allows 'at-risk' patients to be identified so that preventative interventions can be put in place to reduce the risk of ulcer development.

In clinical practice, risk assessment scales are commonly used to give some structure to the assessment process, in preference to clinical 'assessment' or 'judgement' of risk. Nixon and McGough[118] noted that there were > 40 pressure ulcer risk assessment scales, with the majority being developed from a literature review, expert opinion and/or adaptation of an existing scale. They noted that there were only seven 'original' scales. Many were developed in the 1970s and 1980s when the epidemiological evidence was limited by the primary research, including there being few studies considering the relative contribution of individual risk factors. This led to the inconsistent inclusion of risk factors between different scales, with the variables most frequently incorporated being continence/moisture, nutrition/appetite and mobility.[118] This raises concern about the lack of agreement about what should be included in risk assessment scales to adequately identify risk and, as a result, the validity of those scales.[118,119] In addition, existing scales tend to use ordinal scoring systems in which a comparison is made between the patient and a standard reference value to allocate a level of risk (e.g. high risk, moderate risk, at risk), with equal weighting usually given to included risk factors despite the fact that some may be more predictive than others. It has been argued that pressure ulcer risk assessment scales need to be developed on the basis of multivariable analyses to identify factors that are independently associated with pressure ulcer development[118,120,121] and to advance our understanding of the relative contribution that different risk factors make to pressure ulcer development. Gold standard methods for the development of risk stratification tools include multivariable modelling (either from single studies or from meta-analysis from a number of studies) to identify items for a risk tool, with subsequent model testing on a 'new' prospective target population.[122] This type of tool development has in the main been undertaken only in single-centre populations, with methodological limitations including inadequate sample sizes for both model derivation and testing.[123–125]

From a practical perspective there are also issues with the use of existing risk assessment scales. Many were designed to identify risk status in patients without pressure ulcers, but in practice are often used for all patients, including those with and without pressure ulcers and do not distinguish between these groups. This is a limitation as nurses could discount an existing pressure ulcer in their clinical assessment and fail to instigate suitable secondary prevention and treatment interventions, which could lead to deterioration and the development of a more severe pressure ulcer.[126] This resonates with findings from the severe pressure ulcer study (see *Chapter 4*). This is important as the pain cohort study (see *Chapter 3*)

and a recent systematic review of pressure ulcer risk factors,[46] conducted as part of this programme grant, indicated that the presence of a category 1 pressure ulcer is a key predictor of the subsequent development of a category 2 or above pressure ulcer, increasing the odds by two- to threefold.[126]

Increasing evidence makes it timely to reconsider which risk factors should be considered in pressure ulcer risk assessment, how these should be assessed and the overall assessment process in the development of a Risk Assessment Framework. Furthermore, the systematic review[46] conducted as part of this programme highlighted the need to agree a pressure ulcer risk factor Minimum Data Set and further develop a pressure ulcer conceptual framework. These would encourage the use of consistent factors across studies, facilitating meta-analysis, provide a standardised data set for case-mix adjustment and provide the fundamental components for pressure ulcer risk assessment in clinical practice.

Aim

The overall aim of this work package was to agree a pressure ulcer risk factor Minimum Data Set to underpin the development and validation of a Risk Assessment Framework for use in clinical practice. (Note: as outlined in *Chapter 1*, *Pressure ulcer development*, the Risk Assessment Framework is not intended for the prevention or management of ulcers caused by medical devices as the primary risk factor for such ulcers is the presence of the device.)

Research overview

The methodological approach to the development of the Minimum Data Set and Risk Assessment Framework comprised five distinct phases: (1) developing the evidence base, (2) a consensus study, (3) conceptual framework development, (4) design and pre-testing and (5) clinical evaluation (*Figure 11*).

Phase 1: systematic review of patient risk factors for pressure ulcer development

To provide the foundation for the risk assessment work package and to ensure consideration of potential risk factors for inclusion in the Minimum Data Set and Risk Assessment Framework, a systematic review of primary research was undertaken to identify risk factors that are independently predictive of pressure ulcer development in adult patient populations.

Methods

This *Methods* section has been largely reprinted with minor modifications from *Int J Nurs Stud*, vol. 50, Coleman S, Gorecki S, Nelson E, Closs S, Defloor T, Halfens R, *et al*. Patient risk factors for pressure ulcer development: systematic review, pp. 974–1003, 2013,[46] with permission from Elsevier.

Design

The approach was based on the systematic review methods recommended for questions of effectiveness[20,127] and adapted to identify risk factor studies, with consideration of the methodological limitations including bias and confounding associated with observational studies.[83,85]

Study eligibility

Methodological quality criteria were integrated into the inclusion and exclusion criteria of the systematic review, developed from principles of good research conduct in observational studies and randomised controlled trials that minimise bias.[82,86,89,128]

Inclusion criteria

Studies were included if they met the following criteria: primary research; adult study populations in any setting; outcome was the development of a new pressure ulcer(s); prospective cohort study, retrospective record review or a controlled trial; length of follow-up of at least 3 days, with the exception of operating room studies for which no minimal time period was set; outcome clearly defined as grade/stage 1 or

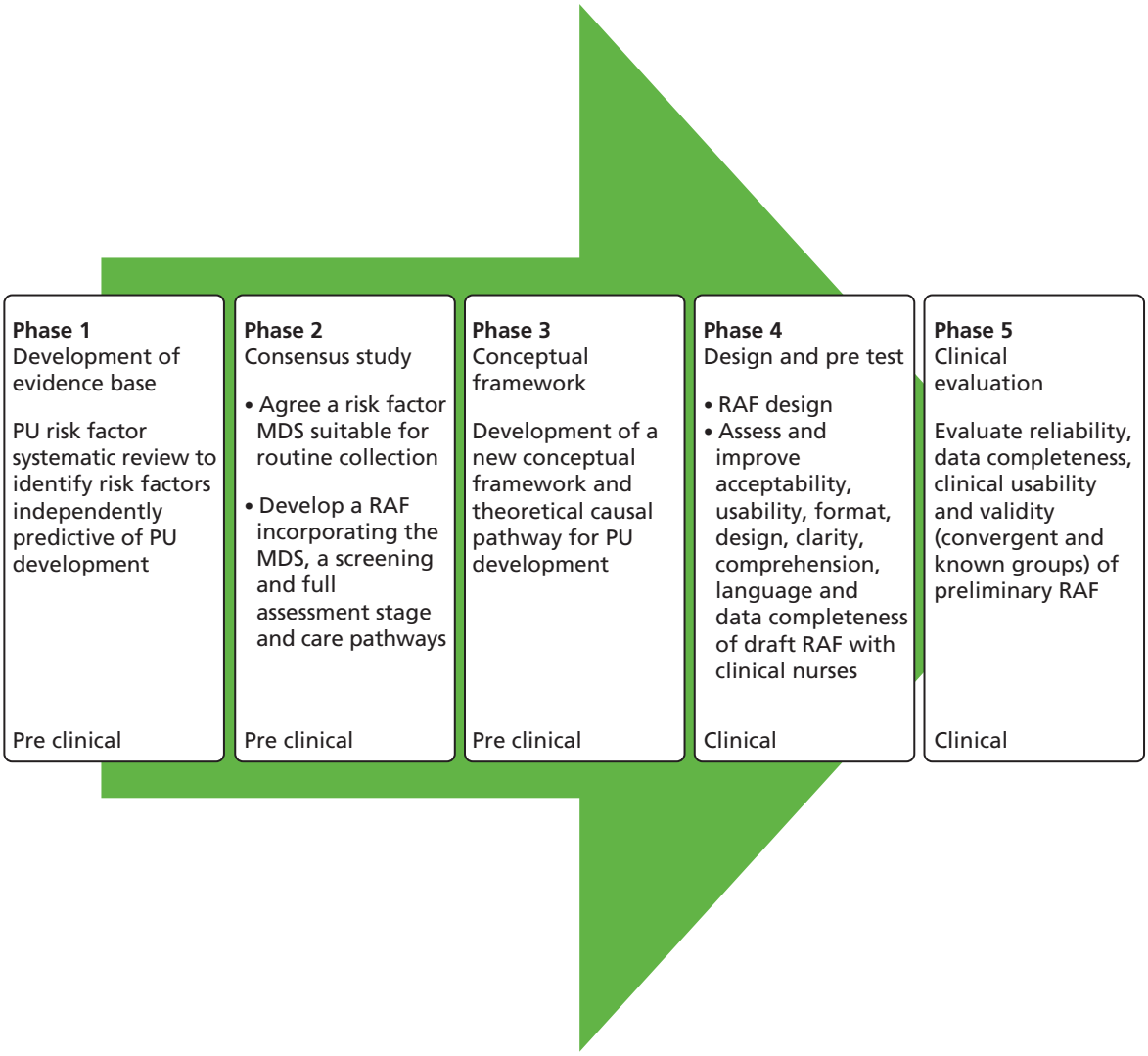

FIGURE 11 Risk Assessment Framework: related studies. MDS, minimum data set; PU, pressure ulcer; RAF, Risk Assessment Framework.

above pressure ulcer[23,129] or equivalent; multivariable analyses were undertaken to identify factors affecting pressure ulcer outcome; and the unit of analysis was the patient.

Exclusion criteria

Studies were excluded as follows: paediatric study populations; cross-sectional or case study designs; patient recall, patient self-report or an analysis of general practitioner records to assess outcome; or duplicate publications of a patient data set. Cohort studies (prospective and record reviews) were excluded from the review if > 20% of the study sample was excluded from analysis for reasons including withdrawal, death, loss to follow-up and missing records.[82,83,86,89] Controlled trials were excluded unless the following minimum criteria applied: randomised allocation to treatment and intention-to-treat analyses.[127,128] No language restriction was applied.

Data sources

Fourteen electronic databases were searched, from inception until March 2010: Allied and Complementary Medicine Database (AMED), British Nursing Index (BNI), MEDLINE, EMBASE, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Library, ProQuest, Networked Digital Library of Theses and Dissertations, International Theses in Progress, Theses Canada Portal, Australian Digital Theses Program, Russian Academy of Sciences Bibliographies and Index to Theses. The search strategy (see *Appendix 14*) sought to identify all published and unpublished research studies investigating risk

factors for the development of pressure ulcers. The search strategy was designed with guidance from the collaborative team and included pressure ulcer search terms,[130] Ovid maximum sensitivity filters for prognosis and aetiology or harm and an Ovid maximum sensitivity filter for randomised controlled trials.[127]

In addition, we hand searched specialist journals and conference proceedings, contacted 13 experts, searched the UK national research websites and performed a citation search on all included studies and systematic reviews identified in the search (see *Appendix 14*).

Study selection

Abstracts were screened for relevance by one reviewer (CG) and checked by a second (JN). Articles assessed as potentially relevant were obtained in full and reviewed against the eligibility criteria by one reviewer (CG or SC) and checked by another (JN). When the statistical methods were unclear and eligibility could not be determined, statistical review was undertaken (JB). Disagreements were dealt with through consensus.

Data extraction

When studies fulfilled the eligibility criteria data were extracted by a single reviewer (CG or SC) and checked by a second reviewer (JN). When data were missing from the publication, attempts were made to contact the authors. When duplicate publications of patient data sets were identified, the most detailed report was used for data extraction. Experts in the field were asked to review/data extract abstracts and articles not published in English (see *Acknowledgements*).

Quality assessment

There are no guidelines for the quality assessment of risk factor studies and so we developed an assessment framework based on guidelines for assessing quality and risk of bias in prognostic studies and on methodological considerations in the analysis, meta-analysis and publication of observational studies.[81–89] Each study was appraised by two reviewers (JN, SC) and the following methodological limitations were noted when present: baseline characteristics not adequately described; inadequate measurement of risk factors (e.g. record review); inappropriate cut-points used for continuous data; and time-dependent covariates included in the analysis without appropriate adjustment.

In addition, specific consideration was given to the following criteria:

1. Is there a sufficient number of events (rule of thumb: ≥ 10 events per risk factor)?
2. Are there sufficient data to assess the adequacy of the methods and analysis?
3. Is the strategy for model building (i.e. inclusion of variables) appropriate and based on a conceptual framework?
4. Is the selected model adequate for the design?

Each of the four criteria was assessed to see whether or not they were met (yes/no/partial/unsure), which provided a structured approach for the classification of overall study quality. We classified studies as being of high, moderate, low and very low quality using the following criteria:

- high-quality studies: 'yes' for all criteria
- moderate-quality studies: 'yes' for criterion 1 and at least two other criteria
- low-quality studies: 'no' for criterion 1 and 'no' or 'partial' for two other criteria
- very low-quality studies: 'no' for criterion 1 and 'no' or 'partial' for all three remaining criteria.

Data synthesis

Meta-analysis of the data was not feasible for this review because of heterogeneity in the study designs, patient populations, risk factor descriptors, interventions used and outcomes reported. As the main aim was to identify risk factors rather than quantify the effect size of the relationship between these factors and pressure ulcer development, a narrative synthesis was carried out.[127]

For each study, all factors entered into multivariable modelling and those that emerged as significant ($p \leq 0.05$) were identified. For studies using stepwise regression, we included non-significant factors ($p \geq 0.05$) if these were reported in the final model as being independently associated with pressure ulcer development.

Risk factors were categorised into domains and subdomains by collating related factors from the source articles into a grouping (domain). An example of a domain and subdomain would be the domain of skin/ulcer status and the subdomains of stage/grade 1, existing pressure ulcer, previous pressure ulcer and general skin status. Evidence tables (see *Appendix 15* for an example), were generated for each risk factor subdomain, with a summary narrative synthesis by subdomain and domain. For each subdomain, the total number of studies entering the variable, the total number of studies in which the variable emerged in the multivariable analyses and the quality of the studies are summarised. In the evidence tables (see *Appendix 15* for an example), grade and stage of pressure ulcer are recorded as reported in individual studies.

Results

The numbers of studies considered and meeting the eligibility criteria are shown in the study flowchart (*Figure 12*). The 54[37,57,60,79,80,125,131–178] included studies included 34,449 patients from acute and community populations.[46]

Study quality

The included studies comprised seven high-quality, 10 moderate-quality, 27 low-quality and 10 very low-quality studies (*Table 29*). The low- and very low-quality studies had inadequate numbers of pressure ulcers and other methodological limitations.

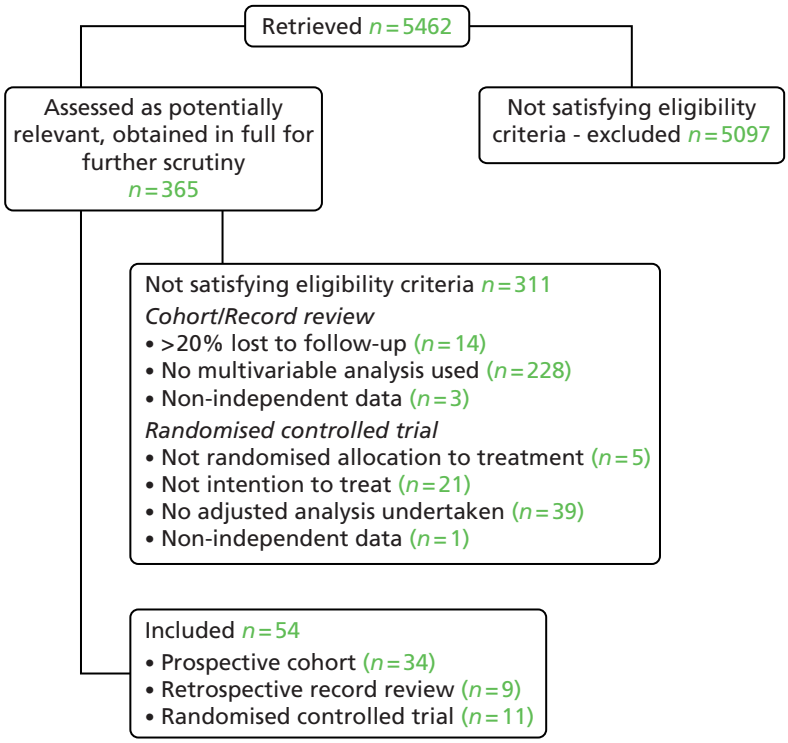

FIGURE 12 Flowchart of studies. Reprinted from *Int J Nurs Stud*, vol. 50, Coleman S, Gorecki C, Nelson EA, Close SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: systematic review. 2013; 974–1003,[46] with permission from Elsevier.

TABLE 29 Summary of included studies

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Allman *et al.* 1995[79] USA	286 patients Setting: acute care hospital Specialty: multiple	Admitted to hospital within previous 3 days, aged ≥ 55 years, expected LOS in bed or chair ≥ 5 days, had a hip fracture, expected LOS (hospital) ≥ 5 days. Excluded patients with stage 2 or above PU, Friday admissions, active skin disease that would interfere with PU assessment and previous enrolment to study. Consent required	Cohort Backward stepwise Cox regression	286 (12.9%), 37 stage ≥ 2	9 (5)				LQS
					Non-blanchable erythema if intact sacral skin	0.05	7.5	1.0 to 59.1	Insufficient number of events
					Immobility	0.02	2.4	1.1 to 4.9	
					Dry sacral skin	0.04	2.3	1.0 to 5.2	
					Decreased body weight	0.03	2.2	1.1 to 4.5	
					Lymphopenia	0.003	4.9	1.7 to 13.9	
Baldwin and Ziegler 1998[131] USA	36 patients Setting: acute care hospital Specialty: trauma	Adults aged 15–60 years, hospitalised because of severe trauma, previously healthy, did not require burn fluid resuscitation and expected LOS (hospital) ≥ 1 week	Cohort Forward logistic regression	36 (30.6%), 11 stage ≥ 1	7 (2)				VLQS
					Braden mobility subscore	0.02	0.3	0.1 to 0.8	Baseline characteristics not reported; sample size too small; insufficient number of events
					Braden moisture subscore	0.04	3.0	1.1 to 8.3	
Bates-Jensen *et al.* 2007[132] USA	35 non-surgical patients Setting: nursing home Specialty: elderly/ geriatric	Long-stay residents in two nursing homes eligible for a larger nutrition trial (not referenced) and provided informed written consent	Cohort Generalised logistic regression	35 (45.7%), 16 stage ≥ 2	5 (2)				LQS
					Subepidermal moisture (at 1 week)	≤ 0.05	1.0	1.004 to 1.012	Inadequate sample size resulting in wide CIs
					Total Braden scale score	≤ 0.05	6.8	0.6 to 72.3	

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Baumgarten *et al.* 2004[133] USA	2285 non-surgical patients Setting: long-term nursing care/ nursing home Specialty: NR	Patients aged ≥ 65 years, newly admitted to nursing home, black or white skin colour, consent or relative assent. Excluded if previously resided in a nursing home or chronic care facility for ≥ 8 days in the year before the nursing home admission	Cohort Cox proportional hazards model	1938 (23.2%), 450 stage ≥ 2	12 (3)				MQS All risk factors are categorical data rather than continuous data; 20% missing data in the final model
					Black race	0.032	1.3	1.0 to 1.7	
					Number of ADL dependencies	0.001	1.4	1.3 to 1.5	
					PU on admission	0.001	1.8	1.4 to 2.3	
Bergquist and Frantz 1999[134] USA	1711 non-surgical patients Setting: community/home care Specialty: elderly/ geriatric	Home health-care agency, aged ≥ 60 years, no PU on admission, non-hospice, non-intravenous therapy. Consent not required	Record review Stepwise Cox proportional hazards model	1567 (3.2%), 55 stage ≥ 2	45 (10)				LQS Record review; insufficient number of events; inadequate measurement of risk factors
					Limited to wheelchair	0.0198	2.8	1.2 to 6.5	
					ADL dressing	< 0.001	2.7	1.5 to 4.8	
					Incontinence bowel and/or bladder	0.0195	2.8	1.2 to 6.8	
					Braden mobility subscore	< 0.001	5.2	2.4 to 11.1	
					Anaemia	0.0021	4.0	1.6 to 9.5	
					Adult child primary caregiver	< 0.001	5.8	2.1 to 15.9	
					Male	0.0281	1.9	1.1 to 3.2	
					Recent fracture	0.0019	3.5	1.6 to 7.6	
					Oxygen use	< 0.001	3.9	2.1 to 7.6	
					Skin drainage	< 0.001	6.6	2.3 to 19.2	

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Bergstrom and Braden 1992[135] USA	200 non-surgical patients Setting: long-term nursing care/nursing home Specialty: elderly/geriatric	Consecutive patient admissions to teaching nursing home were screened and included if aged > 65 years, at risk of PU development (Braden score ≤ 17), free of existing PU, estimated LOS > 10 days. Consent required from patient or family	Cohort Logistic regression (backward elimination)	200 (73.5%), 147 stage ≥ 1; (38.5%), 77 stage ≥ 2 Model 1: stage ≥ 1; model 2: stage ≥ 2; model 3: stage = 1	Model 1: 10 (5)				MQS No CIs reported
					Braden scale score	< 0.01	NR	NR	
					Diastolic BP	< 0.01	NR	NR	
					Temperature	NS	NR	NR	
					Age	NS	NR	NR	
					Protein (% RDA)	< 0.05	NR	NR	
					Model 2: 10 (4)				
					Braden scale score	< 0.001	NR	NR	
					Age	< 0.05	NR	NR	
					Systolic BP	< 0.01	NR	NR	
					Protein (% RDA)	NS	NR	NR	
					Model 3: 10 (4)				
					Braden scale score	< 0.01	NR	NR	
					Diastolic BP	< 0.01	NR	NR	
					Temperature	< 0.05	NR	NR	
					Iron (% RDA)	< 0.01	NR	NR	

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Bergstrom *et al.* 1996[136] USA	843 patients Setting: multiple Specialty: multiple	Patients from two nursing homes, two university hospitals and two VAMCs, aged ≥ 19 years, no PU on admission, admitted for care within 72 hours	Cohort Logistic regression	843 (12.8%), 108 stage ≥ 1 Model 1: age, gender, race, Braden scale score and preventative measures; model 2: mobility, activity and presence or not of 13 listed primary diagnoses; model 3: Braden scale total score and presence or not of 13 listed primary diagnoses	Model 1: 6 (3)				HQS
					Braden scale score	< 0.001	1.3	1.2 to 1.4	
					Age	< 0.001	1.0	0.95 to 0.98	
					Race	0.012	2.7	1.3 to 6.0	
					Model 2: 15 (3)				
					Braden mobility subscore	< 0.001	1.7	1.3 to 2.3	
					Braden activity subscore	0.004	1.5	1.1 to 1.9	
					Cardiovascular disease	0.023	2.5	1.1 to 5.5	
					Model 3: 14 (1)				
					Braden total score	< 0.001	1.4	1.3 to 1.5	
Berlowitz and Wilking 1989[137] USA	185 non-surgical patients Setting: chronic care hospital Specialty: medicine	All admissions to chronic care hospital (requiring medical, skilled nursing or rehabilitative services) with chronic medical conditions. Patients excluded if died or discharged within 1 week of admission or required transfer to an acute care hospital within 24 hours of admission (i.e. had PU at baseline). Consent not required – record review	Cohort Stepwise logistic regression	185 (10.8%), 20 stage ≥ 2	11 (3)				LQS Insufficient number of events; data collection relied on clinical staff; only partial reporting of baseline characteristics
					Cerebrovascular accident	< 0.05	5.0	1.7 to 14.5	
					Bed or chair bound	< 0.05	3.8	1.0 to 14.0	
					Impaired nutritional intake	< 0.05	2.8	1.0 to 17.9	

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Bostrom *et al.* 1996[138] USA	112 patients Setting: multiple Specialty: multiple	Medical and surgical patients admitted to three hospitals (tertiary, general, community) aged ≥ 18 years, able to give consent and expected LOS (hospital) ≥ 48 hours	Cohort Logistic regression	112 (8.04%), 9 stage ≥ 1	7 (1) Number of layers between patient and mattress	0.001	NR	NR	VLQS Insufficient number of events; analysis reporting inadequate; no CIs reported; time-dependent variables included in the analysis
Bourdel-Marchasson *et al.* 2000[139] France	672 patients Setting: acute care hospital Specialty: elderly/ geriatric	Patients recruited from university hospital wards and geriatric units (with > 40% of inpatients aged > 65 years), including neurology, gastroenterology, orthopaedic or vascular surgery, internal and geriatric medicine. Patients aged > 65 years, in acute phase of a critical illness, unable to move or eat independently, no PU on admission. Consent requirement not reported	RCT Cox proportional hazards model	672 (44.5%), 299 stage ≥ 1	NR (5) Hypoalbuminaemia Lower limb fracture Norton score 5–10 vs. > 14 Kuntzman score Control vs. nutritional intervention	< 0.001 < 0.001 0.04 0.003 0.04	1.1 2.7 1.3 1.2 1.6	1.0 to 1.1 1.8 to 4.1 1.0 to 1.6 0.3 to 4.6 1.0 to 2.4	MQS Full details of modelling not provided; adequate number of events is assumed as large number of events ($n = 299$)
Boyle and Green 2001[140] UK	534 patients Setting: ICU Specialty: intensive care	ICU patients not consented. PUs developing after day 1 of admission included in the analysis; those with PU on admission excluded	Cohort Parametric survival regression (Weibull)	534 (5.2%), 28 grade ≥ 1	7 (2) Coma/ unresponsiveness/ paralysed and sedated Cardiovascular instability	0.001 0.035	4.2 2.7	30 to 77 4 to 70	LQS Baseline characteristics not reported; insufficient number of events

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Brandeis *et al.* 1994[141] USA	4232 non-surgical patients Setting: long-term nursing care/ nursing home Specialty: elderly/ geriatric	Residents aged > 60 years, admitted to nursing home during 1988 and 1989, no PU on admission and at 3 months' FU (baseline assessment) Eligible residents remained in the home for ≥ 3 months after baseline assessment up to 21 months. Consent not required – record review	Cohort Pooled logistic regression	4232 (12.9%), 546 stage ≥ 2 Model 1, high-incidence homes: 1322 (19.3%), 255 stage ≥ 2; model 2, low-incidence homes: 1365 (6.5%), 89 stage ≥ 2	Model 1: 15 (4) Ambulation difficulty Faecal incontinence Diabetes Model 2: 15 (3) Ambulation difficulty ADL feeding Male	 < 0.001 < 0.001 < 0.006 < 0.001 < 0.001 < 0.001 < 0.007	 3.3 2.5 1.7 2.2 3.6 3.5 1.9	 2.0 to 5.3 1.6 to 4.0 1.2 to 2.5 1.5 to 3.3 1.7 to 7.4 2.0 to 6.3 1.2 to 3.6	HQS Record review
Chan *et al.* 2005[142] Singapore	666 patients Setting: acute care hospital Specialty: multiple	All hospital inpatients on census date, aged > 18 years. Excluded infectious disease wards, aggressive psychiatric or airborne infectious patients, patients with existing ulcers	Cohort Logistic regression	666 (8.1%), 54 stage ≥ 1	23 (1) Braden score (Braden score 12–15) (Braden score 6–11)	 0.001 0.001 0.001	 7.0 12.5	 3.5 to 17.1 4.5 to 34.6	LQS Only partial reporting of baseline characteristics; inadequate reporting of analysis and modelling; inadequate number of events
Cobb *et al.* 1997[143] USA	123 patients Setting: acute care hospital Specialty: intensive care	Aged > 18 years, weight ≤ 290 lb, no pre-existing PU, expected LOS 1–2 weeks, determined to be at risk based on Braden scale score. Consent required. All hospital wards and ICU of a large military hospital	RCT Wilcoxon test	123 (16.3%), 20 stage ≥ 1	4 (2) Hypertension Weight	 0.03 0.05	 NR NR	 NR NR	VLQS Inadequate reporting of analysis methods; no CIs reported; insufficient number of events

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Compton *et al.* 2008[144] German	713 patients Setting: acute care hospital, non-surgical Specialty: intensive care	Patients without a PU on admission to the medical ICU between April 2001 and December 2004. Patients in the ICU for < 72 hours were excluded from analysis	Record Review	698 (17%), 121 grades 2–4	32 (6)				LQS Record review; large number of events but used 32 variables in the model; no CIs reported
					Male gender	0.014	1.8	NR	
					Moist skin	0.001	2.4	NR	
					Oedematous skin	0.002	2.2	NR	
					Centralised circulation	0.001	2.4	NR	
					Mottled skin	0.016	2.0	NR	
					Reddened skin	0.001	2.3	NR	
Defloor and Grypdonck 2005[57] Belgium	1772 non-surgical patients Setting: long-term nursing care/ nursing home Specialty: elderly/ geriatric	All inpatients in 11 long-term care facilities during the 4-week study period	RCT Stepwise logistic regression	1458 Model 1: 302/1458 (20.7%) grade ≥ 1; model 2: 171/1458 (11.7%) grade ≥ 2	Model 1: 19 (3)				HQS Limitation is the partial reporting of baseline characteristics
					Braden sensory perception subscore	0.02	0.8	0.6 to 1.0	
					Skin condition	< 0.001	1.5	1.2 to 1.9	
					Existing PU	< 0.001	2.3	1.4 to 3.5	
					Model 2: 19 (4)				
					Braden activity subscore	0.03	0.7	0.5 to 1.0	
					Braden sensory perception subscore	0.02	0.7	0.6 to 1.0	
					Skin condition	< 0.001	1.6	1.3 to 2.1	
					Existing PU	0.01	1.9	1.1 to 3.0	

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
De Laat *et al.* 2007[145] Netherlands	399 patients Setting: acute care hospital Specialty: intensive care	Patients admitted into ICU with expected LOS > 48 hours, without PU on admission and screened within 48 hours of admission. Consent not required	Cohort Cox proportional hazards model	399 (35.1%), 140 grade ≥ 2	11 (3) Preventative transfers Shock/resuscitation Friction/shear	< 0.001 < 0.001 0.02	0.2 1.5 1.3	NR NR NR	MQS Ward staff recorded data; no CIs reported; time-dependent covariates included in the analysis
Donnelly 2006[146] UK	240 hip fracture patients Setting: acute care hospital Specialty: elderly/ geriatric	Aged ≥ 65 years on day of injury, new fractured hip (injury < 48 hours 'old'), able to undergo tests and assessment procedures. Patient consent required	RCT Cox proportional hazards model	239 (16.3%), 39 grade ≥ 1	20 (1) Control group (standard mattress)	0.001	4.6	NR	LQS Insufficient number of events; no CI reported
Ek 1987[147] Sweden	515 non-surgical patients Setting: chronic care hospital Specialty: medicine	Consecutive patients admitted to a long-term medical ward who were hospitalised for > 3 days, with or without a PU at baseline. Consent requirement not reported	Cohort Logistic regression	515 (7.6%), 39 ≥ stage 1-equivalent PU Model 1: baseline measures; model 2: variables on day of PU or if PU free in fourth week of care	Model 1: 8 (1) Norton mobility Model 2: 8 (2) General physical condition Norton activity	< 0.05 < 0.01 < 0.01	NR NR NR	NR NR NR	VLQS Partial reporting of baseline characteristics; inadequate reporting of methods; insufficient number of events; no CIs reported
Ek *et al.* 1991[148] Sweden	501 non-surgical patients Setting: acute care hospital Specialty: medicine	Newly admitted long-term medical ward admissions who remained in hospital for > 3 weeks. Patient consent required	RCT Multiple regression	495 (10.1%), 51 ≥ stage 1-equivalent PU	NR (4) Albumin Norton mobility Norton activity Food intake	< 0.001 < 0.001 < 0.001 < 0.05	NR NR NR NR	NR NR NR NR	VLQS Partial reporting of baseline characteristics; inadequate reporting of methods and analysis; no CIs reported; adequacy of number of events cannot be assessed

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Feuchtinger *et al.* 2006[149] Germany	175 surgical patients Setting: acute care hospital Specialty: cardiac surgery	Aged ≥ 18 years, scheduled for cardiac surgery with electrocardiogram, not included in another study. Consent required	RCT Logistic regression	175 (14.3%), 25 grade ≥ 1	13 (1) Renal insufficiency	0.05	NR	NR	LQS Inadequate reporting of analysis; insufficient number of events; no CIs reported
Fife *et al.* 2001[150] USA	186 patients Setting: ICU Specialty: intensive care	Patients admitted to neuro-ICU (acute SCI/head injuries/gunshot wounds/ CVAs). No consent required (apart for photographs). Excluded if more than two PUs on initial assessment, discharge from unit < 24 hours after admission, diagnosis of brain death or life support pending organ donation, no evaluation by nursing staff within 12 hours after admission	Cohort Stepwise logistic regression	149 (15.4%), 23 stage ≥ 2	11 (2) Braden score Age	0.002 0.043	NR NR	NR NR	LQS Insufficient number of events; ORs and CIs not reported
Goodridge *et al.* 1998[151] Canada	330 non-surgical patients Setting: acute care hospital Specialty: elderly/ geriatric	Medical/elderly of tertiary care and long-term care facilities, aged > 65 years, within 48–96 hours of admission. Excluded pre-existing dermal ulcers, terminal stage cancer, acute/chronic renal failure	Cohort Stepwise logistic regression	330 (9.7%), 32 stage ≥ 1	5 (1) Number of prevention strategies used prior to PU appearance	< 0.001	1.4	NR	VLQS Partial presentation of baseline data; nutritional factors collected but not analysed; analysis reporting inadequate; no CI reported; insufficient number of events; time-dependent variable included in the analysis

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Gunningberg *et al.* 2001[152] Sweden	146 hip fracture patients Setting: acute care hospital Specialty: trauma	Patients with hip fracture, aged ≥ 65 years, admitted without a PU, assessments carried out in A&E or orthopaedic department. Not sure about consent – assume not	Record review Logistic regression	146 (36.9%), 54 stage ≥ 1	3 (1) Advanced age	0.03	1.1	NR	MQS Partial reporting of baseline characteristics and analysis reporting inadequate; no CI reported
Halfens *et al.* 2000[153] Netherlands	320 patients Setting: acute care hospital Specialty: multiple	Three hospitals; patients from surgical, neurological, orthopaedic and internal medicine wards. No PU on admittance, Caucasian, probable LOS (hospital) ≥ 10 days. Consent required	Cohort Stepwise logistic regression	320 (14.7%), 47 grade ≥ 1	16 (4) Braden sensory perception subscore Age Braden friction/shear subscore Braden moisture subscore	< 0.01 < 0.01 < 0.01 < 0.01	3.7 2.3 2.3 2.1	1.4 to 9.3 1.4 to 3.9 1.4 to 4.0 1.2 to 3.5	LQS Partial reporting of baseline characteristics; insufficient number of events
Hatanaka *et al.* 2008[154] Japan	149 non-surgical patients Setting: acute care hospital Specialty: respiratory	Bedridden patients hospitalised for a respiratory disorder, required constant attentive care or needed a considerable amount of assisted care	Cohort Cox proportional hazards model	149 (25.5%), 38 grade ≥ 2	NR (5) Haemoglobin C-reactive protein Albumin Age Gender	0.006 0.042 0.021 0.953 0.379	1.2 1.9 0.4 1.0 0.7	1.1 to 1.4 1.0 to 3.9 0.2 to 0.9 0.97 to 1.03 0.3 to 1.7	LQS Clinical data collection method not reported and number of factors entered into the stepwise procedure not reported, therefore adequacy of number of events cannot be assessed

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Inman *et al.* 1999[155] Canada	149 patients Setting: ICU Specialty: intensive care	Aged ≥ 17 years, APACHE II score ≥ 15, expected LOS (ICU) ≥ 3 days. Patients excluded if PUs at baseline, not expected to survive, admitted for compassionate care or ICU transfer. Consecutive admissions randomised – not concealed allocation, consent procedure not detailed	RCT Stepwise logistic regression	144 (25.7%), 37 stage ≥ 1	9 (2) LOS in ICU Increase in SURE score	 NR NR	 NR NR	 NR NR	VLQS Poor quality reporting; insufficient number of events; limited number of risk factors; inadequate statistical reporting and the independent variable is a composite score that includes the dependent variable; *p*-values, ORs and CIs not reported; data reporting by ward staff; time-dependent variables included in the analysis (LOS and increase in SURE score)
Kemp *et al.* 1993[156] USA	84 non-surgical patients Setting: multiple Specialty: elderly/ medical	Patients recruited from hospital inpatient (general medicine and geriatric medicine) and long-term care facilities. Included if aged ≥ 65 years, Braden scale score ≤ 16 and PU free. Consent requirements not detailed	RCT Cox regression	84 (39.3%), 33 stage ≥ 1	11 (2) Overlay type Average Braden mobility subscore	 0.018 < 0.001	 NR NR	 NR NR	LQS Inadequate number of events; CIs not reported

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Lindgren *et al.* 2004[157] Sweden	548 mixed patients Setting: acute care hospital Specialty: multiple	Elective and acute medical or surgical patients admitted to 21 wards in university hospital, aged > 17 years, expected LOS (hospital) ≥ 5 days, for patients undergoing surgery expected time on operating table ≥ 1 hour and PU free. Verbal consent required (patient or relative). Consecutive patients admitted in 3 defined days included up to maximum of nine per week	Cohort Multiple stepwise logistic regression	530 (11.7%) 62 stage ≥ 1 Model 1: total sample; model 2: medical patients: 244 (8.6%) 21 stage ≥ 1; model 3: surgical patients: 286 (14.3%) 41 stage ≥ 1	Model 1: 13 (5)				LQS Insufficient number of events; time-dependent covariate was included in the analysis
					Mobility RAPS scale	0.011	0.5	0.3 to 0.9	
					Length of hospitalisation	0.002	1.0	1.0 to 1.1	
					Age	0.014	1.0	1.0 to 1.1	
					Weight	0.006	1.0	0.9 to 1.0	
					Surgical treatment	< 0.001	4.8	2.0 to 11.4	
					Model 2: 13 (3)				
					Mobility RAPS scale	0.001	0.4	0.2 to 0.6	
					Length of hospitalisation	0.029	1.0	1.00 to 1.04	
					Diastolic BP	0.026	1.0	0.9 to 1.0	
					Model 3: 13 (3)				
					Serum albumin RAPS scale	0.029	0.5	0.3 to 0.9	
					Length of hospitalisation	0.027	1.0	1.0 to 1.1	
					Weight	0.002	1.0	0.9 to 1.0	

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Marchette *et al.* 1991[158] USA	161 surgical patients Setting: acute care hospital Specialty: intensive care	Patients aged > 59 years in ICU after surgery. Consent not required	Record review Discriminant analysis	161 (39.1%), 63 ≥ stage 2-equivalent PUs	NR (5) Skin redness Days static air mattress for prevention Faecal incontinence Diarrhoea Preoperative albumin	 < 0.001 < 0.001 0.0013 0.0019 0.0028	 NR NR NR NR NR	 NR NR NR NR NR	VLQS Inadequate reporting of methods and analysis; no CIs reported; included time-dependent variables in the analysis; adequacy of number of events cannot be assessed
Nijs *et al.* 2009[159] Belgium	520 patients Setting: acute care hospital, surgical Specialty: intensive care	Expected LOS in surgical ICU of an acute hospital > 24 hours. Excluded if aged < 16 years and admitted for burn injuries	Cohort Multivariate logistic regression	463 (28.9%), 134 grades 2–4	19 (9) Dopamine < 5 µg/kg/minute Medical history of vascular disease Intermittent haemodialysis or continuous veno-venous haemofiltration Adequate prevention Frequency of turning six or more times a day or alternating mattress Turning Use of sedatives Body temperature ≥ 38.5 °C Sitting in chair	 0.003 < 0.001 0.045 0.002 < 0.001 < 0.001 0.006 0.029 < 0.001	 6.1 4.5 3.8 6.0 30.2 6.7 0.3 0.2 0.1	 1.9 to 19.5 2.0 to 10.2 1.0 to 13.9 1.9 to 18.6 12.2 to 74.8 2.7 to 16.4 0.1 to 0.7 0.2 to 0.9 0.0 to 0.3	MQS Full details of modelling not provided; adequate number of events is assumed as large number of events

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Nixon *et al.* 2006[37] UK	1972 patients Setting: acute care hospital Specialty: multiple	Aged ≥ 55 years, admitted to orthopaedic, vascular, medical or care of elderly wards, acute or elective, expected LOS ≥ 7 days, limited activity or mobility, existing grade 2 PU. Consent required	RCT, Logistic regression	1971 (10.5%), 207 grade ≥ 2	13 (7) Hospital Acute admission Baseline wound Baseline skin trauma Baseline grade 1 Age Diabetes	 0.02 < 0.001 < 0.001 0.05 0.001 0.03 0.047	 3.7 3.0 1.7 2.0 1.0 1.6	 2.3 to 5.9 1.7 to 5.1 1.0 to 2.8 1.3 to 2.9 1.002 to 1.04 1.0 to 2.6	HQS Minor limitation – number of patients in final model NR
Nixon *et al.* 2007[60] UK	109 surgical patients Setting: acute care hospital Specialty: multiple	Aged > 55 years, expected LOS ≥ 5 days, scheduled for elective major general or vascular or acute orthopaedic surgery (average surgical time ≥ 90 minutes), with or without PU at baseline. Consent required	Cohort Forward stepwise logistic regression	97 (15.5%), 15 grade ≥ 2	8 (4) Preoperative albumin Grade 1 equivalent Weight loss Minimum diastolic BP	 0.009 0.008 0.092 0.205	 0.8 7.0 0.3 1.0	 0.7 to 1.0 1.7 to 29.5 0.1 to 1.2 0.9 to 1.0	LQS Inadequate number of events; included time-dependent variables in the analysis
Okuwa *et al.* 2006[160] Japan	259 non-surgical patients Setting: long-term nursing care/nursing home Specialty: elderly/ geriatric	Patients admitted to long-term care facility, aged ≥ 65 years, bedfast, without lower-extremity PU, LOS (hospital) ≥ 14 days, at risk of developing PU. Consent required (patient or family)	Cohort Forward stepwise Cox regression	259 (12.7%), 33 stage ≥ 2	9 (3) Ankle brachial index Length of bedfast period Male gender	 < 0.001 0.003 0.001	 0.1 3 1	 0.0 to 0.2 1.5 to 6.0 1.004 to 1.015	LQS Inadequate number of events; time-dependent variables reported

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Olson *et al.* 1996[161] USA	149 patients Setting: acute care hospital Specialty: multiple	Medical and surgical inpatients aged ≥ 18 years, no PU on admission, expected LOS (hospital) ≥ 5 days. Consent required	Cohort Stepwise logistic regression	143 (13.9%), 20 stage ≥ 1	11 (3) Haemoglobin Hours in bed Pulse pressure	 0.0731 0.0551 0.3022	 NR NR NR	 NR NR NR	LQS Insufficient number of events
Ooi *et al.* 1999[162] USA	5518 non-surgical patients Setting: long-term nursing care/nursing home Specialty: elderly/geriatric	Nursing home residents free from PUs at baseline and 3-month FU assessment. Excluded residents in homes with < 50 beds. Consent not required – record review	Record review Logistic regression backward elimination	5518 (11.4%), 629 stage ≥ 2	6 (6) Age Diabetes Faecal/urine incontinence Transfers Medicaid payments Facility effects Facility effects intermediate risk Facility effects high risk	 0.0081 0.0106 < 0.001 < 0.001 0.0623 < 0.001 < 0.001	 1 1.4 1.6 1.5 1.2 1.6 1.9	 1.00 to 1.03 1.1 to 1.7 1.2 to 2.0 1.2 to 1.8 1.0 to 1.4 1.3 to 2.0 1.5 to 2.4	MQS Record review and limited range of risk factors considered (e.g. do not include mobility in the model)

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Pancorbo Hidalgo and Garcia Fernandez 2001[163] Spain	187 patients Setting: acute care hospital Specialty: multiple	Patients at risk of PUs (Gosnell score ≤ 12) and aged > 70 years, admitted to internal medicine, ICU, general surgery and orthopaedic wards	Cohort Logistic regression	187 (16.6%), 31 stage ≥ 1 Model 1: stage ≥ 1; model 2: stage ≥ 2	Model 1: 16 (9)				LQS Article was translated so unable to undertake detailed quality assessment; limitations based on inadequate number of events; time-dependent variables included in the analysis
					LOS	< 0.05	1.1	1.1 to 1.2	
					Gosnell score	< 0.05	1.2	1.1 to 1.2	
					Incontinence	< 0.05	2.2	1.7 to 2.9	
					Skin alterations diminished	< 0.05	1.4	1.0 to 1.9	
					Highest systolic BP	< 0.05	1	0.9 to 1.0	
					Lowest diastolic BP	< 0.05	1.1	1.06 to 1.13	
					Low skinfold thickness	< 0.05	1.3	1.0 to 1.6	
					Diminished lymphocytes	< 0.05	1.2	1.0 to 1.5	
					Low haemoglobin	< 0.05	2.2	1.3 to 3.9	

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
					Model 2: (10)				
					LOS	< 0.05	1.2	1.1 to 1.2	
					Gosnell score	< 0.05	1.1	1.1 to 1.2	
					Incontinence	< 0.05	1.2	1.1 to 1.2	
					Activity diminished	< 0.05	2	1.2 to 3.5	
					Highest systolic BP	< 0.05	1	0.9 to 1.0	
					Lowest diastolic BP	< 0.05	1.1	1.0 to 1.1	
					Low skinfold thickness	< 0.05	1.4	1.0 to 1.9	
					Diminished lymphocytes	< 0.05	1.5	1.1 to 2.0	
					Low haemoglobin	< 0.05	3	1.5 to 6.1	
					Use of alternating overlay (at-risk patients)	< 0.05	2.7	1.0 to 6.9	

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Perneger *et al.* 2002[164] Switzerland	1190 patients Setting: acute care hospital Specialty: multiple	All newly admitted patients to mixed specialties within a teaching hospital (with or without PU at baseline). Consent not required	Cohort Multivariate proportional hazards model	1190 (10.8%), 129 stage ≥ 1	10 (3)				HQS Limitation is the partial reporting of baseline characteristics
					Braden/Norton mobility subscore	0.006	1.4	1.1 to 1.8	
					Braden friction/shear subscore	0.034	1.5	1.0 to 1.8	
					Age 16–59 years				
					(Age 60–69 years)		1.5	0.8 to 2.2	
					(Age 70–79 years)		2.5	1.5 to 4.4	
					(Age 80–89 years)		3.8	2.3 to 6.4	
					(Age 90–96 years)		5.2	2.6 to 10.6	
Rademakers *et al.* 2007[165] Netherlands	722 hip fracture patients Setting: acute care Specialty: trauma	Hip fracture patients admitted to level 1 trauma centre. Excluded those aged < 60 years, (multiple) high-energy trauma (fall from higher than ground level; road traffic accident), initial conservative treatment, interhospital transfer, presence of PUs on admission, pathological fractures and recurrent fractures	Record review Multivariate logistic regression	722 (29.6%), 214 stage ≥ 2	10 (5)				MQS Large sample size but limited number of risk factors considered and not based on a conceptual framework (no nutrition or skin moisture factors); inadequate measurement of risk factors (record review)
					Diabetes	0.021	1.7	1.1 to 2.7	
					Postoperative urinary tract infection	0.004	1.9	1.2 to 2.9	
					Postoperative hip dislocation	0.009	2.7	1.3 to 5.6	
					ASA class III/IV	0.001	4.2	2.9 to 6.1	
					Time to surgery > 12 hours	0.008	1.7	1.2 to 2.6	

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Reed *et al.* 2003[80] USA	2771 non-surgical patients Setting: chronic care hospital Specialty: medicine	Record review identifying mobility impaired, admitted to the chosen hospital wards between 1 July 1994 and 1 October 1997, LOS ≥ 1 week. Consent not required, grade 3 and 4 PUs reported	Record review Forward stepwise logistic regression	2771 (14.7%), 406 stage ≥ 2	7 (6)				HQS Record review
					Low albumin levels	0.014	1.4	1.1 to 1.8	
					Confusion	0.001	1.5	1.2 to 1.8	
					Do not resuscitate order	< 0.001	1.5	1.2 to 1.9	
					Urinary catheter on admission	< 0.001	1.6	1.4 to 1.8	
					Malnutrition	< 0.001	1.7	1.3 to 2.2	
					Stage 1 PU	< 0.001	3.1	2.4 to 4.1	
Rose *et al.* 2006[166] Canada	111 patients Setting: acute care hospital Specialty: intensive care	Consecutive admissions to university hospital ICU. Consent not reported	Cohort Multiple regression	111 (43.2%), 48 stage ≥ 1	NR (3)				VLQS Abstract only; inadequate information on methodology and analysis; no *p*-values or CIs reported
					Skin quality	NR	NR	NR	
					Restricted movement	NR	NR	NR	
					Temperature	NR	NR	NR	

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Salzberg *et al.* 1999[167] USA	226 SCI patients Setting: acute care hospital Specialty: trauma	SCI with a neurological deficit attributable to damage of the spinal cord, excluding the cortices and brainstem, defined by ICD-9-CM, acute SCI as a result of a trauma, survival ≥ 14 days following acute SCI, level of SCI between C4 and S1	Record review Model 1 forward stepwise linear regression; model 2 Cox proportional hazards model	226 (38.5%), 87 stage ≥ 1	Model 1: 8 (3)				MQS Limited because record review and no CIs reported
					Extent of paralysis	< 0.001	NR	NR	
					Moisture	< 0.001	NR	NR	
					Serum creatinine	0.007	NR	NR	
					Model 2: 8 (8)				
					Extent of paralysis	< 0.001	NR	NR	
					Moisture	0.003	NR	NR	
					Serum creatinine	0.006	NR	NR	
					Incontinence	< 0.001	NR	NR	
					Albumin	0.028	NR	NR	
					Mobility	0.002	NR	NR	
					Pulmonary disease	0.014	NR	NR	
					Level of activity	0.036	NR	NR	
Sayar *et al.* 2009[168] Turkey	140 patients Setting: acute care hospital Specialty: intensive care	Surgical and medical ICU patients. Within 1–2 hours of admission to the ICU, the Waterlow scale was administered; patients scoring 'at risk' and 'very high risk' were included	Cohort Multiple stepwise logistic regression	140 (14.3%), 20 stage ≥ 1	6 (2)				LQS Insufficient number of events
					LOS	< 0.001	1.2	1.1 to 1.3	
					Activity level	0.005	0.3	0.2 to 0.7	

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Schnelle *et al.* 1997[169] USA	105 non-surgical patients Setting: long-term nursing care/nursing home Specialty: elderly/geriatric	Incontinent nursing home residents, consent required. Exclusion criteria were presence of stage 2 or above PU at baseline, use of a catheter, LOS < 60 days	Cohort Stepwise multiple regression	91 (20.9%), 19 stage ≥ 1 Model 1: stage ≥ 1 severity index = NR; model 2: stage ≥ 1 only = NR	Model 1: NR (2) Bed mobility Blanchable erythema severity Model 2: NR (1) Blanchable erythema severity	 NR NR NR	 NR NR NR	 NR NR NR	LQS Insufficient number of events and analysis reporting inadequate; no *p*-values or CIs reported
Schoonhoven *et al.* 2002[170] Netherlands	223 surgical patients Setting: acute care hospital Specialty: multiple	Patients scheduled for surgery expected to exceed 4 hours (post-recruitment exclusion if surgery lasted < 4 hours)	Cohort Multiple logistic regression	208 (10.1), 21 grade ≥ 2	12 (1) Length of surgery (minutes)	 < 0.05	 1.0	 1.0035 to 1.0087	LQS Baseline characteristics not reported; insufficient number of events
Schultz *et al.* 1999[171] USA	413 surgical patients Setting: acute care hospital Specialty: mixed	Patients scheduled for inpatient care, aged ≥ 18 years, with surgery scheduled to last > 2 hours in lithotomy or supine position. Excluded those with PUs at baseline, severe chronic skin problems or receiving only local anaesthesia	RCT Logistic regression	413 (21.5%), 89 stage ≥ 1	7 (5) Age Presence of diabetes Less body mass Use of the study mattress Admission Braden score	 0.005 0.013 0.015 0.044 0.013	 1.1 2.5 0.9 1.9 0.8	 1.0 to 1.1 1.2 to 5.3 0.9 to 1.0 1.0 to 3.7 0.7 to 1.0	HQS Risk factors recorded by operating room and ward staff although outcome data were assessed by research assistants

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Serpa and Santos 2007[172] Brazil	170 patients Setting: private hospital Specialty: NR	Age ≥ 18 years, no PU at admission, hospitalised for ≥ 24 hours, total Braden scale score, admitted to two private hospitals, agreed to participate. Exclusion criteria were chronic renal failure, dialysis treatment for > 1 month or the presence of hepatic insufficiency accompanied by ascites	Cohort Multivariate logistic regression	170 (NR), NR	16 (5) Subjective Global Assessment (for Nutrition) Albumin Urea Age Institution	 < 0.001 < 0.001 < 0.001 < 0.001 < 0.001			LQS Unable to assess in detail as abstract and author communication available only; low-quality study based on assumed inadequate number of events; definition of stage of PU unknown
Stordeur *et al.* 1998[173] Belgium	174 surgical patients Setting: acute care hospital Specialty: cardiac/ vascular	Consecutive patients, aged ≥ 16 years who underwent cardiac or vascular surgery, minimum LOS (hospital) > 5 days. Excluded patients who died. Not sure about consent – assume not	Cohort Stepwise logistic regression	163 (29.5%), 48 stage ≥ 2	16 (3) Postoperative Braden score Haemoglobin concentration at admission Postoperative steroid therapy	 < 0.001 < 0.001 0.02	 NR NR NR	 NR NR NR	LQS Insufficient number of events; CIs not reported
Suriadi *et al.* 2007[174] Indonesia	105 patients Setting: ICU Specialty: intensive care	Admitted to ICU for ≥ 24 hours and expected LOS (ICU) ≥ 3 days, bedfast or unable to walk, free from PUs, informed consent (by patient or family). Excluded patients who were physically incapable of participating (difficult to identify skin condition daily as patient could not be manipulated) or who did not wish to participate	Cohort Multivariate logistic regression	105 (33.3%), 35 stage ≥ 1	6 (4) Interface pressure Skin moisture Smoking > 10 cigarettes per day Body temperature	 < 0.001 0.002 0.001 0.001	 17.6 8.2 12.7 102	 4.1 to 74.3 2.2 to 30.9 2.8 to 56.7 7.7 to 98.8	LQS Insufficient number of events

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Suriadi *et al.* 2008[125] Japan	253 patients Setting: acute care hospital Specialty: intensive care	ICU patients aged > 18 years, admitted at least 24 hours before study enrolment, bedfast, no existing PU, able to give informed consent and of Indonesian origin	Cohort Logistic regression model	253 (28.4%), 72 stage ≥ 1	Unknown (3) Interface pressure Body temperature Cigarette smoking		 2.2 2 1.6	 1.6 to 2.9 1.7 to 2.5 1.1 to 2.5	MQS Inadequate reporting of analysis and modelling; adequate number of events is assumed as large number of events
Tourtual *et al.* 1997[175] USA	291 non-surgical patients Setting: acute care hospital Specialty: medicine, elderly/ geriatric	All patients admitted to four nursing units within an acute hospital, consent given. Baseline PU status not recorded	Cohort Forward stepwise logistic regression	291 (21.6%), 63 stage ≥ 1 heel PU	17 (2) Braden friction and sheer subscore Braden moisture subscore	 0.01 0.007	 NR NR	 NR NR	LQS Insufficient number of events; CIs not reported
Vanderwee *et al.* 2009[176] Belgium	235 patients Setting: nursing home Specialty: elderly non-surgical	Nursing home patients with no PU (grades 2–4 according to EPUAP), able to be repositioned, expected LOS > 3 days in the nursing home and with non-blanchable erythema at pressure points on the skin	RCT Multivariate Cox regression analysis	235 (18.7%), 44 grade ≥ 2	16 (6) Age > 80 to 90 years Age > 90 years CVA Urinary incontinence Dual incontinence Contractures Hypotension	 0.16 0.015 0.042 0.004 0.086 0.04 0.002	 0.6 0.4 1.9 0.2 0.5 2 3.4	 0.3 to 1.2 0.2 to 0.8 1.1 to 3.7 0.1 to 0.6 0.2 to 1.1 1.0 to 4.0 1.6 to 7.5	LQS Insufficient number of events

continued

TABLE 29 Summary of included studies (*continued*)

Study and country	Study population	Other inclusion criteria	Design and analysis method	Number in final model (PU%), number developing PU and stage/grade	Results: *n* risk factors (*n* in model), model risk factor names	*p*-value[a]	OR[b]	CI[b]	Overall study quality[c] and limitation notes
Watts *et al.* 1998[177] USA	148 patients Setting: acute care Specialty: trauma	Victims of blunt or penetrating injury, traumatic injury, aged ≥ 15 years, LOS ≥ 2 days and no pre-existing PU	Cohort Logistic regression	148 (20. 3%), 30 stage ≥ 1	20 (1) Braden mobility subscore	NR	7.5	NR	VLQS Baseline characteristics not reported; insufficient number of events and presentation of analysis; inadequate measurement of risk factors; no CI or *p*-value reported
Yepes *et al.* 2009[178] Colombia	150 patients Setting: acute care hospital Specialty: intensive care	Patients without PUs on admission, hospitalised for > 48 hours in the ICU and with any of the following risk factors for PUs: intubated and on mechanical ventilation, with vasopressor support	Cohort Multivariate logistic regression	150 (26.7%), 40 stage ≥ 2	8 (3) Infection ICU LOS APACHE II	 0.023 0.005 0.044	 2.9 1.1 1.1	 1.2 to 7.2 1.1 to 1.2 1 to 1.1	LQS Insufficient number of events; time-dependent variable included in the analysis

A&E, accident and emergency; ADL, activities of daily living; APACHE, Acute Physiology and Chronic Health Evaluation; ASA, American Society of Anesthesiologists; BP, blood pressure; CVA, cerebrovascular accident; FU, follow-up; ICD-9-CM, *International Classification of Diseases*, Ninth Revision, Clinical Modification; ICU, intensive care unit; LOS, length of stay; NR, not reported; NS, not significant; PU, pressure ulcer; RAPS, Risk Assessment Pressure Sore; RCT, randomised controlled trial; RDA, recommended daily allowance; SCI, spinal cord injury; SURE, Skin Ulcer Risk Evaluation; VAMC, Veteran's Administration Medical Center.

a *p*-values < 0.001 reported as such.

b ORs and CIs reported to one decimal place (where appropriate).

c Overall study quality: HQS, high-quality study; MQS, moderate-quality study; LQS, low-quality study; VLQS, very low-quality study.

Source: Reprinted from *Int J Nurs Stud*, vol. 50, Coleman S, Gorecki C, Nelson EA, Close SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: systematic review. 2013; 974–1003,[46] with permission from Elsevier.

Emerging risk factor domains/subdomains

The review identified 15 risk factor domains and 46 subdomains (*Table 30*). The number and quality of studies in which associated risk variables emerged in multivariable modelling and the number and quality of studies in which associated risk variables did not emerge are detailed in *Table 30* [full evidence tables are available at: http://medhealth.leeds.ac.uk/downloads/download/657/systematic_review_evidence_tables (accessed August 2015)]. The review highlighted three primary risk factor domains:

1. Mobility/activity (immobility), with the subdomains of mobility subscales, mobility/activity, activities of daily living (ADL) and activity (bedfast/chairfast/immobile descriptors) emerging most consistently.
2. Skin/ulcer status, with the subdomain of stage/grade 1 pressure ulcer emerging most consistently. General skin status was also found to be important but the diverse variables (e.g. dry sacral skin, mottled skin, unhealthy skin, skin redness, baseline skin trauma) made interpretation difficult.
3. Perfusion, with the subdomain of diabetes emerging strongly in the high-/moderate-quality studies. Evidence from the large number of other perfusion-related variables suggests that factors that impair circulation increase the probability of pressure ulcer development but the evidence is limited by the large range of variable descriptors and study quality. Further research is needed in this area.

TABLE 30 Summary of evidence for risk factor domains/subdomains

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
Mobility/activity subdomains		
Risk Assessment Scale mobility subscale 8/14 studies (57.1%)	1 HQS – Perneger *et al.*[164] 3 LQS – Bergquist and Frantz;[134] Lindgren *et al.*;[157] Kemp *et al.*[156] 4 VLQS – Baldwin and Ziegler;[131] Watts *et al.*;[177] Ek;[147] Ek *et al.*[148]	1 MQS – Salzberg *et al.*[167] 4 LQS – Vanderwee *et al.*;[176] Tourtual *et al.*;[175] Pancorbo Hidalgo and Garcia Fernandez;[163] Halfens *et al.*[153] 1 VLQS – Bostrom *et al.*[138]
Risk Assessment Scale activity subscale 1/16 studies (6.2%)	1 VLQS – Ek *et al.*[148]	3 HQS – Defloor and Grypdonck;[57] Perneger *et al.*;[164] Nixon *et al.*[37] 1 MQS – Salzberg *et al.*[167] 7 LQS – Bergquist and Frantz;[134] Vanderwee *et al.*;[176] Tourtual *et al.*;[175] Pancorbo Hidalgo and Garcia Fernandez;[163] Halfens *et al.*;[153] Lindgren *et al.*;[157] Kemp *et al.*[156] 4 VLQS – Baldwin and Ziegler;[131] Watts *et al.*;[177] Bostrom *et al.*;[138] Ek[147]
Activity (bedfast/chairfast/immobile) descriptors 6/11 (54.5%)	1 MQS – Nijs *et al.*[159] 5 LQS – Schnelle *et al.*;[169] Olson *et al.*;[161] Allman *et al.*;[79] Berlowitz and Wilking;[137] Okuwa *et al.*[160]	2 MQS – De Laat *et al.*;[145] Baumgarten *et al.*[133] 3 LQS – Fife *et al.*;[150] Bergquist and Frantz;[134] Donnelly[146]
Mobility/activity ADL 4/7 (57.1%)	1 HQS – Brandeis *et al.*[141] 1 MQS – Ooi *et al.*[162] 1 LQS – Sayar *et al.*[168] 1 VLQS – Rose *et al.*[166]	1 MQS – Rademakers *et al.*[165] 2 LQS – Bergquist and Frantz;[134] Donnelly[146]
General ADL 2/4 (50%)	1 MQS – Baumgarten *et al.*[133] 1 LQS – Bergquist and Frantz[134]	1 HQS – Brandeis *et al.*[141] 1 LQS – Berlowitz and Wilking[137]

continued

TABLE 30 Summary of evidence for risk factor domains/subdomains (*continued*)

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
RAS friction and shear	1 HQS – Perneger *et al.*[164]	1 HQS – Defloor and Grypdonck[57]
4/12 (33.3%)	1 MQS – De Laat *et al.*[145]	4 LQS – Bergquist and Frantz;[134] Vanderwee *et al.*;[176] Lindgren *et al.*;[157] Kemp *et al.*[156]
	2 LQS – Tourtual *et al.*;[175] Halfens *et al.*[153]	3 VLQS – Baldwin and Ziegler;[131] Watts *et al.*;[177] Bostrom *et al.*[138]
Factors affecting mobility	3 MQS – Rademakers *et al.*;[165] Salzberg *et al.*;[167] Bourdel-Marchasson *et al.*[139]	1 HQS – Defloor and Grypdonck[57]
6/13 (46.1%)	3 LQS – Boyle and Green;[140] Bergquist and Frantz;[134] Vanderwee *et al.*[176]	1 MQS – De Laat *et al.*[145]
		5 LQS – Fife *et al.*;[150] Sayar *et al.*;[168] Tourtual *et al.*;[175] Berlowitz and Wilking;[137] Feuchtinger *et al.*[149]
Interface pressures	1 MQS – Suriadi *et al.*[125]	
2/2 (100%)	1 LQS – Suriadi *et al.*[174]	
Skin/PU status subdomains		
Stage/grade 1	2 HQS – Reed *et al.*;[80] Nixon *et al.*[37]	
4/4 (100%)	2 LQS – Allman *et al.*;[79] Nixon *et al.*[60]	
Existing PU	1 HQS – Defloor and Grypdonck[57]	1 HQS – Nixon *et al.*[37]
2/5 (40%)	1 MQS – Baumgarten *et al.*[133]	2 LQS – Tourtual *et al.*;[175] Stordeur *et al.*[173]
Previous PUs		2 LQS – Allman *et al.*;[79] Halfens *et al.*[153]
0/2 (0%)		
General skin status	2 HQS – Defloor and Grypdonck;[57] Nixon *et al.*[37]	1 LQS – Boyle and Green[140]
9/10 (90%)	5 LQS – Compton *et al.*;[144] Schnelle *et al.*;[169] Allman *et al.*;[79] Pancorbo Hidalgo and Garcia Fernandez;[163] Bates-Jensen *et al.*[132]	
	2 VLQS – Rose *et al.*;[166] Marchette *et al.*[158]	
Perfusion subdomains		
Diabetes	3 HQS – Schultz *et al.*;[171] Brandeis *et al.*;[141] Nixon *et al.*[37]	7 LQS – Compton *et al.*;[144] Vanderwee *et al.*;[176] Berlowitz and Wilking;[137] Stordeur *et al.*;[173] Halfens *et al.*;[153] Feuchtinger *et al.*;[149] Donnelly[146]
5/12 (41.6%)	2 MQS – Rademakers *et al.*;[165] Ooi *et al.*[162]	
Vascular disease	1 MQS – Nijs *et al.*[159]	2 LQS – Tourtual *et al.*;[175] Donnelly[146]
4/6 (66.6%)	3 LQS – Vanderwee *et al.*;[176] Berlowitz and Wilking;[137] Feuchtinger *et al.*[149]	
Circulation	3 LQS – Compton *et al.*;[144] Olson *et al.*;[161] Okuwa *et al.*[160]	1 HQS – Defloor and Grypdonck[57]
3/6 (50%)		2 LQS – Tourtual *et al.*;[175] Feuchtinger *et al.*[149]
Blood pressure	1 MQS – Bergstrom and Braden[135]	5 LQS – Fife *et al.*;[150] Suriadi *et al.*;[174] Olson *et al.*;[161] Lindgren *et al.*;[157] Donnelly[146]
6/11 (54.5%)	4 LQS – Boyle and Green;[140] Vanderwee *et al.*;[176] Pancorbo Hidalgo and Garcia Fernandez;[163] Nixon *et al.*[60]	
	1 VLQS – Cobb *et al.*[143]	

TABLE 30 Summary of evidence for risk factor domains/subdomains (*continued*)

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
Smoking	1 MQS – Suriadi *et al.*[125]	2 LQS – Feuchtinger *et al.*;[149] Donnelly[146]
2/4 (50%)	1 LQS – Suriadi *et al.*[174]	
Oedema	1 LQS – Compton *et al.*[144]	1 MQS – Nijs *et al.*[159]
1/4 (25%)		2 LQS – Bergquist and Frantz;[134] Donnelly[146]
Haematological measures subdomains		
Urea and electrolytes	1 MQS – Salzberg *et al.*[167]	2 LQS – Berlowitz and Wilking;[137] Okuwa *et al.*[160]
2/4 (50%)	1 LQS – Serpa and Santos[172]	
Protein	1 LQS – Hatanaka *et al.*[154]	1 LQS – Sayar *et al.*[168]
1/3 (33.3%)		1 VLQS – Marchette *et al.*[158]
Albumin	1 HQS – Reed *et al.*[80]	2 MQS – Bergstrom and Braden;[135] Salzberg *et al.*[167]
7/11 (63.6%)	1 MQS – Bourdel-Marchasson *et al.*[139]	2 LQS – Lindgren *et al.*;[157] Kemp *et al.*[156]
	3 LQS – Serpa and Santos;[172] Hatanaka *et al.*;[154] Nixon *et al.*[60]	
	2 VLQS – Ek *et al.*;[148] Marchette *et al.*[158]	
Lymphopenia	2 LQS – Allman *et al.*;[79] Pancorbo Hidalgo and Garcia Fernandez[163]	
2/2 (100%)		
Haemoglobin	1 HQS – Nixon *et al.*[37]	1 MQS – Gunningberg *et al.*[152]
6/11 (54.5%)	5 LQS – Hatanaka *et al.*;[154] Bergquist and Frantz;[134] Olson *et al.*;[161] Stordeur *et al.*;[173] Pancorbo Hidalgo and Garcia Fernandez[163]	4 LQS – Serpa and Santos;[172] Feuchtinger *et al.*;[149] Nixon *et al.*;[60] Okuwa *et al.*[160]
Moisture subdomains		
Moisture subscales	1 MQS – Salzberg *et al.*[167]	2 HQS – Defloor and Grypdonck;[57] Perneger *et al.*[164]
4/12 (33.3%)	2 LQS – Tourtual *et al.*;[175] Halfens *et al.*[153]	
	1 VLQS – Baldwin and Ziegler[131]	3 LQS – Bergquist and Frantz;[134] Vanderwee *et al.*;[176] Kemp *et al.*[156]
		3 VLQS – Watts *et al.*;[177] Bostrom *et al.*;[138] Ek[147]
Urinary incontinence	1 LQS – Vanderwee *et al.*[176]	1 HQS – Brandeis *et al.*[141]
1/7 (14.3%)		2 MQS – Salzberg *et al.*;[167] Baumgarten *et al.*[133]
		3 LQS – Bergquist and Frantz;[134] Halfens *et al.*;[153] Donnelly[146]
Faecal incontinence	1 HQS – Brandeis *et al.*[141]	1 HQS – Reed *et al.*[80]
2/11 (18.2%)	1 VLQS – Marchette *et al.*[158]	1 MQS – Baumgarten *et al.*[133]
		7 LQS – Boyle and Green;[140] Fife *et al.*;[150] Suriadi *et al.*;[174] Olson *et al.*;[161] Allman *et al.*;[79] Halfens *et al.*;[153] Donnelly[146]

continued

TABLE 30 Summary of evidence for risk factor domains/subdomains (*continued*)

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
Dual incontinence 3/5 (60.0%)	1 MQS – Ooi *et al.*[162] 2 LQS – Bergquist and Frantz;[134] Vanderwee *et al.*[176]	1 MQS – Baumgarten *et al.*[133] 1 LQS – Tourtual *et al.*[175]
Incontinence other 1/1 (100%)	1 LQS – Pancorbo Hidalgo and Garcia Fernandez[163]	
Urinary catheter 1/3 (33.3%)	1 HQS – Reed *et al.*[80]	2 LQS – Compton *et al.*;[144] Berlowitz and Wilking[137]
Skin moisture 3/5 (60.0%)	3 LQS – Suriadi *et al.*;[174] Compton *et al.*;[144] Bergquist and Frantz[134]	1 MQS – De Laat *et al.*[145] 1 LQS – Halfens *et al.*[153]
Body temperature domain		
Body temperature 5/8 (62.5%)	3 MQS – Nijs *et al.*;[159] Suriadi *et al.*;[125] Bergstrom and Braden[135] 1 LQS – Suriadi *et al.*[174] 1 VLQS – Rose *et al.*[166]	2 LQS – Vanderwee *et al.*;[176] Feuchtinger *et al.*[149] 1 VLQS – Ek[147]
Nutrition subdomains		
Nutritional scales 1/14 (7.1%)	1 LQS – Serpa and Santos[172]	3 HQS – Defloor and Grypdonck;[57] Perneger *et al.*;[164] Nixon *et al.*[37] 6 LQS – Vanderwee *et al.*;[176] Tourtual *et al.*;[175] Pancorbo Hidalgo and Garcia Fernandez;[163] Halfens *et al.*;[153] Lindgren *et al.*;[157] Kemp *et al.*[156] 4 VLQS – Baldwin and Ziegler;[131] Watts *et al.*;[177] Bostrom *et al.*;[138] Ek[147]
Food intake 4/7 (57.1%)	1 HQS – Brandeis *et al.*[141] 1 MQS – Bergstrom and Braden[135] 1 LQS – Berlowitz and Wilking;[137] 1 VLQS – Ek *et al.*[148]	1 HQS – Defloor and Grypdonck[57] 1 MQS – De Laat *et al.*[145] 1 LQS – Bergquist and Frantz[134]
Malnourishment 1/3 (33.3%)	1 HQS – Reed *et al.*[80]	2 LQS – Schoonhoven *et al.*;[170] Donnelly[146]
Weight 4/12 (33.3%)	3 LQS – Allman *et al.*;[79] Lindgren *et al.*;[157] Nixon *et al.*[60] 1 VLQS – Cobb *et al.*[143]	1 MQS – Bergstrom and Braden[135] 5 LQS – Yepes *et al.*;[178] Boyle and Green;[140] Compton *et al.*;[144] Olson *et al.*;[161] Kemp *et al.*[156] 2 VLQS – Inman *et al.*;[155] Watts *et al.*[177]
BMI 2/9 (22.2%)	1 HQS – Schultz *et al.*[171] 1 LQS – Fife *et al.*[150]	2 HQS – Defloor and Grypdonck;[57] Brandeis *et al.*[141] 5 LQS – Serpa and Santos;[172] Compton *et al.*;[144] Vanderwee *et al.*;[176] Feuchtinger *et al.*;[149] Lindgren *et al.*[157]

TABLE 30 Summary of evidence for risk factor domains/subdomains (*continued*)

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
Arm measurements 1/3 (33.3%)	1 LQS – Pancorbo Hidalgo and Garcia Fernandez[163]	2 LQS – Serpa and Santos;[172] Allman *et al.*[79]
Other measures 0/4 (0%)		2 LQS – Yepes *et al.*;[178] Compton *et al.*[144] 2 VLQS – Inman *et al.*;[155] Watts *et al.*[177]
Age domain		
Increasing age 12/32 (37.5%)	4 HQS – Schultz *et al.*;[171] Perneger *et al.*;[164] Bergstrom *et al.*;[136] Nixon *et al.*[37] 3 MQS – Ooi *et al.*;[162] Bergstrom and Braden;[135] Gunningberg *et al.*[152] 5 LQS – Serpa and Santos;[172] Hatanaka *et al.*;[154] Vanderwee *et al.*;[176] Halfens *et al.*;[153] Lindgren *et al.*[157]	2 HQS – Defloor and Grypdonck;[57] Brandeis *et al.*[141] 2 MQS – De Laat *et al.*;[145] Baumgarten *et al.*[133] 12 LQS – Chan *et al.*;[142] Yepes *et al.*;[178] Fife *et al.*;[150] Compton *et al.*;[144] Bergquist and Frantz;[134] Tourtual *et al.*;[175] Olson *et al.*;[161] Allman *et al.*;[79] Berlowitz and Wilking;[137] Feuchtinger *et al.*;[149] Kemp *et al.*;[156] Nixon *et al.*[60] 4 VLQS – Inman *et al.*;[155] Watts *et al.*;[177] Goodridge *et al.*;[151] Cobb *et al.*[143]
Sensory perception domain		
Braden sensory perception subscale 2/9 (22.2%)	1 HQS – Defloor and Grypdonck[57] 1 LQS – Halfens *et al.*[153]	1 HQS – Perneger *et al.*[164] 3 LQS – Vanderwee *et al.*;[176] Tourtual *et al.*;[175] Kemp *et al.*[156] 3 VLQS – Baldwin and Ziegler;[131] Watts *et al.*;[177] Bostrom *et al.*[138]
Mental status subdomains		
Mental status subscales 1/5 (20%)	1 HQS – Perneger *et al.*[164]	1 HQS – Defloor and Grypdonck[57] 2 LQS – Pancorbo Hidalgo and Garcia Fernandez;[163] Donnelly[146] 1 VLQS – Ek[147]
Mental status study-specific measures 1/8 (12.5%)	1 HQS – Reed *et al.*[80]	1 HQS – Brandeis *et al.*[141] 1 MQS – Baumgarten *et al.*[133] 5 LQS – Bergquist and Frantz;[134] Sayar *et al.*;[168] Pancorbo Hidalgo and Garcia Fernandez;[163] Halfens *et al.*;[153] Donnelly[146]
Race domain		
Race 2/5 (40%)	1 HQS – Bergstrom *et al.*[136] 1 MQS – Baumgarten *et al.*[133]	1 HQS – Brandeis *et al.*[141] 2 LQS – Bates-Jensen *et al.*;[132] Chan *et al.*[142]

continued

TABLE 30 Summary of evidence for risk factor domains/subdomains (*continued*)

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
Gender domain		
Gender 4/15 (26.6%)	4 LQS – Compton *et al.*;[144] Bergquist and Frantz;[134] Okuwa *et al.*;[160] Hatanaka *et al.*[154]	2 HQS – Brandeis *et al.*;[141] Bergstrom *et al.*[136] 1 MQS – Baumgarten *et al.*[133] 6 LQS – Chan *et al.*;[142] Serpa and Santos;[172] Boyle and Green;[140] Fife *et al.*;[150] Lindgren *et al.*;[157] Donnelly[146] 2 VLQS – Inman *et al.*;[155] Goodridge *et al.*[151]
General health status subdomains		
ASA 1/2 (50%)	1 MQS – Rademakers *et al.*[165]	1 LQS – Donnelly[146]
APACHE II 1/4 (25%)	1 LQS – Yepes *et al.*[178]	1 MQS – Nijs *et al.*[159] 1 LQS – Compton *et al.*[144] 1 VLQS – Inman *et al.*[155]
Norton score measures 0/3 (0%)		2 HQS – Defloor and Grypdonck;[57] Perneger *et al.*[164] 1 VLQS – Ek[147]
Chronic wounds 1/2 (50%)	1 HQS – Nixon *et al.*[37]	1 LQS – Nixon *et al.*[60]
Other factors 8/26 (30.8%)	3 HQS – Schultz *et al.*;[171] Reed *et al.*;[80] Nixon *et al.*[37] 2 MQS – Rademakers *et al.*;[165] Nijs *et al.*[159] 2 LQS – Yepes *et al.*;[178] Lindgren *et al.*[157] 1 VLQS – Marchette *et al.*[158]	2 HQS – Defloor and Grypdonck;[57] Brandeis *et al.*[141] 2 MQS –Salzberg *et al.*;[167] De Laat *et al.*[145] 12 LQS – Bates-Jensen *et al.*[132] Chan *et al.*;[142] Serpa and Santos;[172] Schoonhoven *et al.*;[170] Fife *et al.*;[150] Compton *et al.*;[144] Bergquist and Frantz;[134] Halfens *et al.*;[153] Feuchtinger *et al.*;[149] Nixon *et al.*;[60] Okuwa *et al.*;[160] Donnelly[146] 2 VLQS – Inman *et al.*;[155] Watts *et al.*[177]
Medication domain		
Medication 3/10 (30%)	1 MQS – Nijs *et al.*[159] 2 LQS – Bergquist and Frantz;[134] Stordeur *et al.*[173]	1 HQS – Brandeis *et al.*[141] 6 LQS – Yepes *et al.*;[178] Schoonhoven *et al.*;[170] Compton *et al.*;[144] Vanderwee *et al.*;[176] Olson *et al.*;[161] Donnelly[146]

TABLE 30 Summary of evidence for risk factor domains/subdomains (*continued*)

Domain summary: variable significant/total number studies entered variable (%)	Number and quality of studies variable significant in multivariable model[a]	Number and quality of studies variable non-significant in multivariable model[a]
Risk factor subdomains		
Braden scale total score 7/16 (43.75%)	2 HQS – Schultz *et al.*;[171] Bergstrom *et al.*[136] 1 MQS – Bergstrom and Braden[135] 4 LQS – Bates-Jensen *et al.*[132] Chan *et al.*;[142] Fife *et al.*;[150] Stordeur *et al.*[173]	6 LQS – Yepes *et al.*;[178] Serpa and Santos;[172]; Bergquist and Frantz;[134] Tourtual *et al.*;[175] Kemp *et al.*;[156] Donnelly[146] 3 VLQS – Baldwin and Ziegler;[131] Watts *et al.*;[177] Goodridge *et al.*[151]
Other scales 3/7 (42.8%)	1 MQS – Bourdel-Marchasson *et al.*[139] 1 LQS – Pancorbo Hidalgo and Garcia Fernandez[163] 1 VLQS – Inman *et al.*[155]	4 LQS – Compton *et al.*;[144] Sayar *et al.*;[168] Stordeur *et al.*;[173] Lindgren *et al.*[157]

APACHE, Acute Physiology and Chronic Health Evaluation; ASA, American Society of Anesthesiologists.
a Study quality: HQS, high-quality study; MQS, moderate-quality study; LQS, low-quality study; VLQS, very low-quality study.
Source: Reprinted from *Int J Nurs Stud*, vol. 50, Coleman S, Gorecki C, Nelson EA, Close SJ, Defloor T, Halfens R, Farrin A, Brown J, Schoonhoven L, Nixon J. Patient risk factors for pressure ulcer development: systematic review. 2013; 974–1003,[46] with permission from Elsevier.

Other risk factor domains that were less consistently associated with pressure ulcer development included nutrition, moisture, age, haematological measures, general health status, sensory perception and mental status. Additionally, only a small number of studies included body temperature and immunity and these factors require further research. Finally, the evidence related to race and gender as risk factors was equivocal.

The review[46] indicates that there are three primary risk factor domains of mobility/activity, skin/ulcer status and perfusion (including diabetes) but suggests that there is no single factor that can alone explain pressure ulcer development; rather, there is a complex interplay of factors that increases pressure ulcer probability. Although immobility is included in existing pressure ulcer risk assessment tools, the inclusion of skin/ulcer status and perfusion (including diabetes) is not universal. This highlights the need to reconsider the risk factors included in pressure ulcer risk assessment tools.

It is noteworthy that there were a large number of potential risk factors –15 domains and 46 subdomains including over 250 named variables. Furthermore, there was a lack of comparable data fields for measurement of the same constructs and key risk factors were not routinely recorded in all studies.[46] These limitations prevented meta-analysis to identify an item pool for a risk stratification tool and a key recommendation of the review was the development of a Minimum Data Set for pressure ulcer research and institutional cohorts to facilitate future large-scale multivariate analyses and meta-analysis.

Phase 2: consensus study

Although the systematic review[46] provided a foundation for the ongoing work, there remained gaps in the evidence base and a lack of agreement over the key risk factors and data items to summarise patient risk. This highlighted the need to consult with experts in the pressure ulcer field about the relevance of the evidence to clinical practice and risk assessment and about other pertinent scientific (physiological and biomechanical) evidence that ought to be considered to agree the risk factors and items to be included in the Minimum Data Set and Risk Assessment Framework (see *Appendix 16* for study protocol).

Aim and objectives

The *Aims and objectives, Methods* and *Results* sections are largely reproduced, with amendments, from Coleman S, Nelson E, Keen J, Wilson L, McGinnis E, Dealey C, *et al*. Developing a pressure ulcer risk factor minimum data set and risk assessment framework, *J Adv Nurs*, with permission from John Wiley & Sons.[126]

The aim of this study was to develop a draft pressure ulcer risk factor Minimum Data Set and Risk Assessment Framework for pre-testing and clinical evaluation.

The objectives were to:

1. agree a list of patient characteristics to form a Minimum Data Set suitable for routine collection of key risk factors in adult patient populations
2. develop a Risk Assessment Framework incorporating the Minimum Data Set with:

    i. a simple *screening stage* to quickly identify not-at-risk patients
    ii. a detailed *full assessment stage* for patients who are at potential/actual risk or who have an existing pressure ulcer
    iii. decision pathways [i.e. not currently at risk, primary prevention (at risk) or secondary prevention and treatment pathway (with pressure ulcer)].

Methods

Design

A consensus study using a modified nominal group technique based on the RAND/UCLA appropriateness method[179] was used. This incorporated face-to face interaction and pre- and post-meeting questionnaire completion with an expert group, as well as face-to-face interaction with a service user group (PURSUN UK; see *Chapter 2*).

Expert group participants

The expert group comprised international clinical/academic leaders identified through their publication record in pressure ulcer or relevant research (see *Acknowledgements*). The involvement of international expert group members was facilitated by additional funding from a Leeds University World Universities Network grant. The group was purposively sampled to include the perspectives of nurses, doctors, bioengineers, epidemiologists and individuals with organisational development and decision science expertise. A multispecialty group was developed to take account of a wide range of opinions.[180] Seventeen members were recruited to allow for attrition, as 12 was considered the optimum number in terms of preventing co-ordination problems whilst maximising reliability.[181]

Service user group participants

The service user group involved members of PURSUN UK (see *Chapter 2*). All members were invited to take part and seven people have been involved throughout the project. This includes people with experience of having a pressure ulcer or living with pressure ulcer risk as well as carers.

Data collection

The consensus process incorporated an initial expert group meeting and an initial PURSUN UK meeting followed by two consensus cycles. It was envisaged that the first consensus cycle would consider the Minimum Data Set and the second cycle would consider the Risk Assessment Framework; however, at the initial expert group meeting it was apparent that there were difficulties with considering the Minimum Data Set and Risk Assessment Framework separately as the two are interlinked. Discussion at the meeting highlighted the need to identify the key pressure ulcer risk factors and assessment items (i.e. the way in which the risk factors are measured) that would be included in the Minimum Data Set and incorporated in the Risk Assessment Framework. Therefore, the first consensus cycle focused on agreeing the risk factors to be included in the Minimum Data Set and Risk Assessment Framework and the second consensus cycle focused on the assessment items (*Figure 13*). The study was approved by the University of Leeds School of

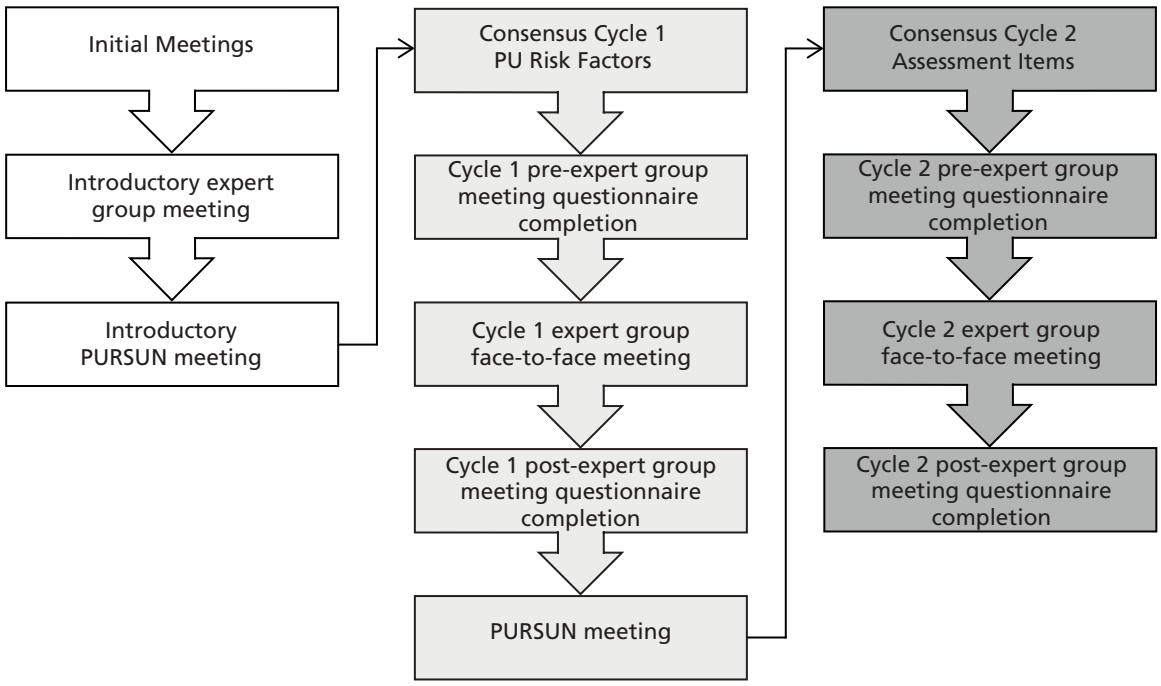

FIGURE 13 Overview of the consensus cycle. PU, pressure ulcer. Reprinted from Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.[126] © 2014 The Authors. *Journal of Advanced Nursing*. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

Healthcare Research Ethics Committee. Informed consent was gained from expert group members prior to participation (see *Appendices 17–22* for participant information and consent forms).

Reviewing the pressure ulcer risk factor evidence was an important element of the study and was integrated throughout all cycles of the consensus process.[46] The systematic review[46] provided evidence regarding the current state of knowledge surrounding pressure ulcer risk factors but the group also considered wider scientific evidence that was drawn from the expertise of the group. The relevance of the evidence to clinical practice, as well as the practicalities of pressure ulcer risk assessment, were also considered by the group.

Questionnaires were completed by all expert group members privately before and after the cycle 1 and 2 meetings (see *Figure 13*). In each questionnaire, participants were asked to rate their level of support for statements (relating to the inclusion of risk factors/assessment items in the Minimum Data Set and Risk Assessment Framework) on a 9-point Likert scale, with 1 indicating strong disagreement and 9 indicating strong agreement. Each statement was preceded by a relevant summary of the pressure ulcer systematic review evidence, as well as a summary of expert group discussions, a summary of PURSUN UK group discussions (as applicable) and follow-up/explanatory notes (as applicable). Electronic links to the full systematic review evidence tables and the full summary of the preceding expert group discussions were also available within the questionnaires. This allowed the research team to identify areas of agreement, uncertainty and disagreement before each meeting and to schedule the discussion agenda accordingly. The completion of the questionnaire after the meeting allowed individuals to change their ratings in light of discussions and/or when necessary allowed questionnaire items to be clarified and amended.

Questionnaires were administered and completed using a commercial online survey platform. Participants were asked to complete the questionnaire within 2 weeks of initial posting. One or two reminders were sent (and on one occasion, because of a holiday period, a third reminder was sent) to participants who had not completed the questionnaire within the allotted 2-week period. The surveys were closed to response at 10 weeks following initial posting.

All expert group meetings were led by trained facilitators and were audiotaped. Unlike a traditional RAND/UCLA method in which the first face-to-face meeting occurs following questionnaire completion, an initial face-to-face meeting was undertaken to review the pressure ulcer evidence and consider the views of the group to inform the development of the cycle 1 risk factor questionnaire.[182] At cycle 1 and 2 expert group meetings (see *Figure 13*), the pre-meeting collective questionnaire responses were anonymously fed back to the group. Members were also provided with a reminder report of their individual questionnaire responses and a copy of the summary of the discussions of the previous expert group meeting. The questionnaire results highlighted areas of agreement and areas of uncertainty and disagreement, which provided a focus for the group discussions to ascertain whether there was genuine uncertainty or disagreement or if there was ambiguity in the wording of the questionnaire.

As pressure ulcer risk assessment practice is part of routine care there was a need to explore the acceptability of proposed risk assessment elements to patients and carers; this was undertaken through facilitated PURSUN UK meetings. PURSUN UK members' views were fed back to the expert group at the subsequent meeting (cycles 1 and 2) and through the cycle 2 pre-meeting questionnaire.

Data analysis

The researcher (SC) listened to the audio tapes of the expert group meetings and read the associated transcripts in total to ensure completeness. The data were then coded, with categories based on the pressure ulcer risk factor systematic review, in keeping with a directed content analysis approach.[183] As new themes emerged from the expert group discussions further codes were added. A summary report of each meeting was generated by the researcher. The report was reviewed by the facilitators and members of the working group (subgroup of the expert group that comprised the local team and incorporated three academic nurses, three clinical nurses, one PPI officer and one member with organisational development expertise) to ensure that it reflected group discussions.

Careful notes were taken throughout the PURSUN UK meetings and a summary of the discussions was written by the researcher (SC). The summary was circulated to the facilitator and group participants to ensure that it reflected the discussions at the meeting.

Questionnaire statements were summarised using the median group response as a measure of central tendency. In keeping with the RAND/UCLA appropriateness methods and other studies[179,184–186] Likert-scale group median responses for each statement were categorised into three tertiles. For this study, the categories were 1–3, disagree; 4–6, uncertain; and 7–9, agree. Within-group agreement was measured using the RAND disagreement index,[179] which considers the dispersion of individual scores and identifies areas of disagreement (when panellists rate at both ends of the Likert scale). An index of > 1 indicates disagreement.

Using the group median response and the disagreement index for each statement (regarding risk factors/assessment items) the following principles were applied following post-meeting questionnaire completion:

- group medians of 1–3 without disagreement would be excluded
- group medians of 7–9 without disagreement would be included
- when the disagreement index was > 1 or when the median was 4–6, group medians would be excluded but noted as potential areas for further research.

Results

The expert group comprised nine female and eight male participants. There was 100% ($n = 68/68$) completion of questionnaires, with 77.9% ($n = 53/68$) completed within the 2-week allotted time period [13.2% (9/68) were completed up to 1 week late; 2.9% (2/68) up to 4 weeks late; 1.5% (1/68) up to 6 weeks late; 1.5% (1/68) up to 7 weeks late; and 2.9% (2/68) up to 8 weeks late]. In total, there was 86.3% attendance at the face-to-face meetings (17/17 attended the first meeting, 13/17 attended the second meeting and 14/17 attended the third meeting). The results concerning the risk factors (cycle 1) and assessment items (cycle 2) of the Minimum Data Set and Risk Assessment Framework are detailed in the following sections.

Cycle 1: risk factors

The expert group agreed that three risk factors should be incorporated into the *screening stage* of the Minimum Data Set and Risk Assessment Framework for the assessment of all patients: immobility, existing pressure ulcer and previous pressure ulcer. *Table 31* shows the changes in questionnaire responses between the pre-meeting questionnaire and the post-meeting questionnaire.

TABLE 31 Risk factors for the screening stage of the Minimum Data Set and Risk Assessment Framework

	Pre-meeting questionnaire responses		Post-meeting questionnaire responses	
Risk factor	Group median	Disagreement index	Group median	Disagreement index
Immobility status	9.00[a]	0.00	9.00[a]	0.00
Existing PU status	9.00[a]	0.13	9.00[a]	0.00
Previous PU status	7.00[a]	0.29	8.00[a]	0.29
General skin status	5.00[b]	1.87[c]	3.00[d]	0.74
Sensory perception	4.00[b]	0.68	3.00[d]	0.72
Acute illness	5.00[b]	0.59	3.00[d]	0.54
Infection	5.00[b]	0.98	2.00[d]	0.33
Body temperature	5.00[b]	0.97	2.00[d]	0.29
Nutrition	5.00[b]	0.55	2.00[d]	0.75
Friction and shear	2.00[d]	0.16	2.00[d]	0.29
Chronic wounds	3.00[d]	0.65	2.00[d]	0.29
Diabetes	4.00[b]	0.55	2.00[d]	0.37
Summary measure GHS	2.00[d]	0.20	2.00[d]	0.13
Perfusion	–	–	2.00[d]	0.75
Albumin	3.00[d]	0.48	2.00[d]	0.29
Skin moisture	4.00[b]	1.61[c]	2.00[d]	0.29
Dual incontinence	5.00[b]	1.70[c]	2.00[d]	0.33
Medication	3.00[d]	0.33	1.00[d]	0.02
Mental health status	2.00[d]	0.65	1.00[d]	0.13
Age	4.00[b]	0.67	1.00[d]	0.16
Race	2.00[d]	0.49	1.00[d]	0.02
Gender	1.00[d]	0.29	1.00[d]	0.02
Haemoglobin	2.00[d]	0.37	1.00[d]	0.16
Pitting oedema	3.00[d]	0.67	1.00[d]	0.13
Blood pressure	3.00[d]	0.67	–	–
Smoking	2.00[d]	0.37	–	–
Cardiovascular disease	3.00[d]	0.67	–	–

GHS, general health status; PU, pressure ulcer.
a Group median 7–9 (inclusion supported).
b Group median 4–6 (uncertain).
c Disagreement.
d Group median 1–3 (inclusion not supported).
Reprinted from Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.[126] © 2014 The Authors. *Journal of Advanced Nursing*. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

The expert group agreed that 11 risk factors, namely immobility, existing pressure ulcer, previous pressure ulcer, general skin status, perfusion, skin moisture, dual incontinence, diabetes, sensory perception, nutrition and albumin level, should be incorporated into the *full assessment stage* of the Minimum Data Set and Risk Assessment Framework for patients who were considered to be at potential/actual risk or who have an existing pressure ulcer identified at the screening stage. *Table 32* shows the changes in questionnaire responses between the pre-meeting questionnaire and the post-meeting questionnaire. A summary of the key discussion points relating to uncertain (group median 4–6) risk factors is detailed in *Table 33*. After reviewing the evidence, the post-meeting questionnaire was revised and blood pressure, smoking and cardiovascular disease were combined into a general category of 'perfusion'.

TABLE 32 Risk factors for the full assessment stage of the Minimum Data Set and Risk Assessment Framework

	Pre-meeting questionnaire responses		Post-meeting questionnaire responses	
Risk factor	Group median	Disagreement index	Group median	Disagreement index
Immobility status	9.00[a]	0.16	9.00[a]	0.00
Existing PU status	9.00[a]	0.13	9.00[a]	0.16
Previous PU status	7.00[a]	0.40	8.00[a]	0.16
General skin status	8.00[a]	0.23	8.00[a]	0.29
Skin moisture	8.00[a]	0.29	8.00[a]	0.33
Diabetes	8.00[a]	0.29	8.00[a]	0.33
Nutrition	7.00[a]	0.67	8.00[a]	0.16
Perfusion	–	–	8.00[a]	0.40
Albumin	7.00[a]	0.20	7.00[a]	0.45
Sensory perception	8.00[a]	0.29	7.00[a]	0.29
Dual incontinence	8.00[a]	0.19	7.00[a]	0.33
Friction and shear	5.00[b]	1.10[c]	6.00[b]	0.52
Chronic wounds	6.00[b]	0.42	6.00[b]	0.37
Medication	5.00[b]	0.41	5.00[b]	0.08
Acute illness	7.00[a]	0.07	5.00[b]	0.59
Infection	5.00[b]	1.10[c]	5.00[b]	0.41
Body temperature	7.00[a]	0.52	5.00[b]	0.88
Pitting oedema	6.00[b]	0.30	5.00[b]	1.04[c]
Age	5.00[b]	0.49	5.00[b]	0.50
Summary measure GHS	4.00[b]	0.62	4.00[b]	0.65
Haemoglobin	5.00[b]	0.32	3.00[d]	0.72
Mental health status	5.00[b]	0.72	2.00[d]	0.75
Race	2.00[d]	0.49	1.00[d]	0.13
Gender	2.00[d]	0.29	1.00[d]	0.02
Blood pressure	5.00[b]	0.52	–	
Smoking	5.00[b]	0.59	–	–
Cardiovascular disease	6.00[b]	0.42	–	–

GHS, general health status; PU, pressure ulcer.
a Group median 7–9 (inclusion supported).
b Group median 4–6 (uncertain).
c Disagreement.
d Group median 1–3 (inclusion not supported).
Source: Reprinted from Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.[126] © 2014 The Authors. *Journal of Advanced Nursing*. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

TABLE 33 Uncertain risk factors

Uncertain risk factors	Key discussion points from the expert group meetings
Friction and shear	• Important concept in relation to biomechanics and tissue loading • Debate about whether a patient characteristic • Difficult to measure in practice • Different definition of terms (e.g. nurses and bioengineers) • Interlinked with immobility • Should to be minimised in care
Acute illness, infection, body temperature (elements of general health status)	• Felt to be important clinically • Links between the three elements recognised • Impact on mobility, perfusion and moisture acknowledged
Chronic wound	• Did not emerge as a strong risk factor in the systematic review • Link to other factors including nutritional depletion, moisture (exudate), oedema, diabetes and general skin condition recognised • Would be captured by other key risk factors, e.g. general skin status, nutrition, moisture and diabetes
Pitting oedema	• Relatively unexplored area in the literature • Leads to changes in the mechanical properties of tissues • May result in reduced mobility because of heavy oedematous legs • Some felt that oedema should be considered under the 'skin status' umbrella
Medication	• Acknowledged that the systematic review evidence associated with medication was weak • Links between specific medications and risk factors were made [e.g. the effects of sedation, epidurals and analgesia on sensation and movement; the effects of steroids on skin condition (tissue paper skin)] • Use of vasoconstrictors in specialist areas important • Complicated by dose-dependent effects • Difficult to measure
Age	• Some felt that age formed an important element of assessment • Others felt that it was a proxy for other measures, e.g. skin condition and immobility

Source: Reprinted from Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.[126] © 2014 The Authors. *Journal of Advanced Nursing*. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

Using the decision rules highlighted in the methods section, the Minimum Data Set and Risk Assessment Framework comprised only those risk factors for which there was agreement (group median 7–9 without disagreement). The progression of risk factors through the consensus study is detailed in *Figure 14* (see also *Tables 31* and *32*). This shows that of the original 15 risk factor domains and 46 subdomains identified in the systematic review,[46] 26 risk factors were considered to potentially warrant inclusion in the Minimum Data Set and Risk Assessment Framework and progressed to consensus cycle 1.

The risk factors for inclusion were mainly agreed in the cycle 1 post-meeting questionnaire but there were some refinements of the risk factors in the cycle 2 pre-meeting questionnaire. The expert group had agreed that albumin should be included at the second stage of the assessment (see *Table 32*). However, at a subsequent PURSUN UK meeting, concern was raised about the need to undertake an *additional* blood test for the assessment of albumin. In light of this, expert group members were asked whether there was a clinical indication for undertaking an additional blood test to measure albumin for patients to establish the level of pressure ulcer risk and it was concluded that this was unnecessary. The expert group also concluded that skin moisture and dual incontinence could be combined into one measure.

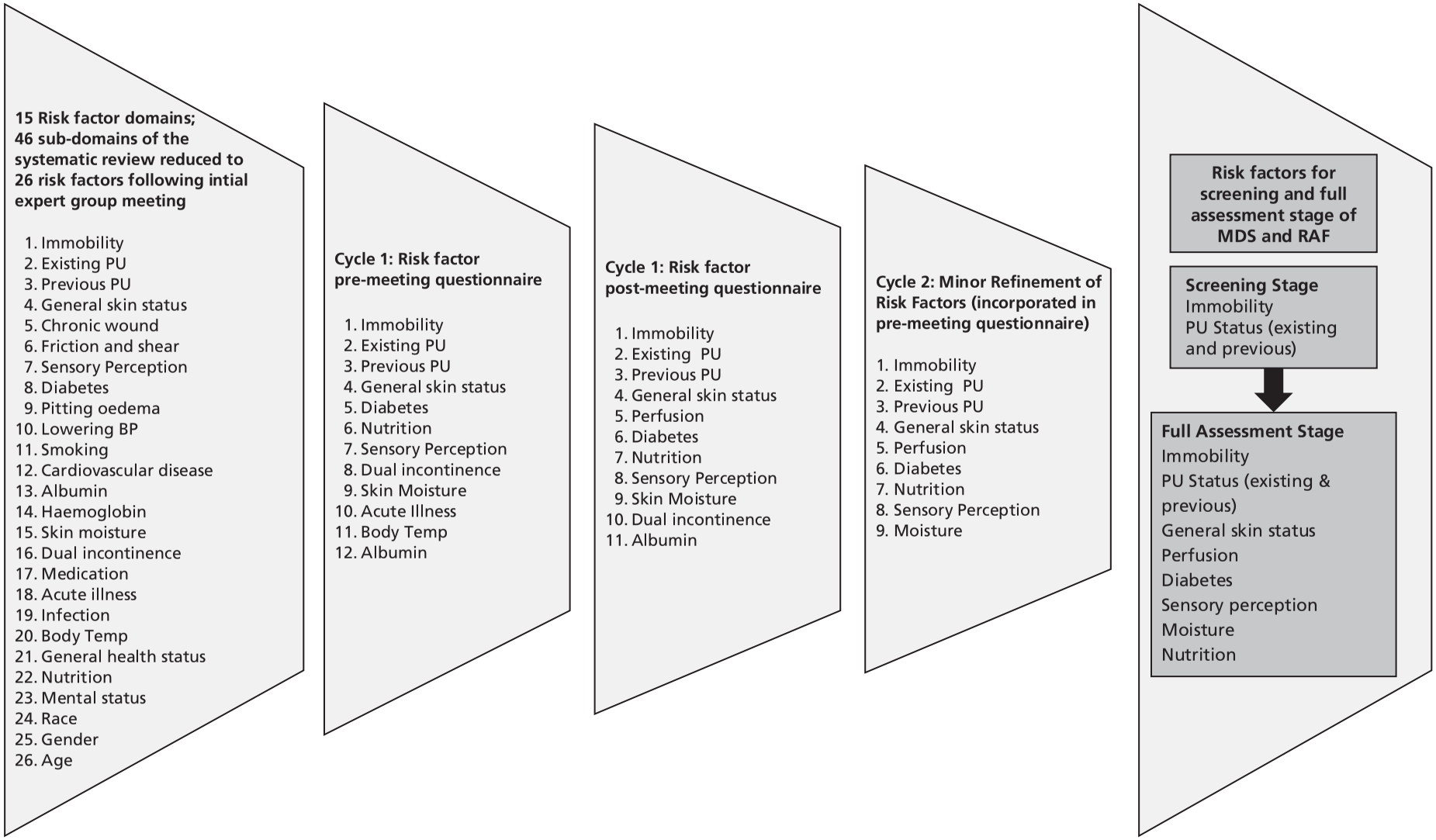

FIGURE 14 Risk factor progression. BP, blood pressure; MDS, minimum data set; PU, pressure ulcer; RAF, Risk Assessment Framework. Reprinted from Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.[126] © 2014 The Authors. *Journal of Advanced Nursing*. Published by John Wiley & Sons Ltd. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

Cycle 2: assessment items for risk factors

There was support (group median 7–9 without disagreement) for all statements in the cycle 2 questionnaire concerning the assessment items of the Minimum Data Set and Risk Assessment Framework. However, following discussion at the cycle 2 meeting, the expert group felt that some changes should be made to specific items. As the group were content with the majority of the pressure ulcer risk factor Minimum Data Set items highlighted in the cycle 2 pre-meeting questionnaire, the post-meeting questionnaire focused on items that required adjustment. The agreed assessment items for the screening and full assessment stage are detailed in *Table 34*. In addition, the expert group agreed that the Risk Assessment Framework would facilitate the identification of a risk profile for each patient, rather than condense the risk from different aspects into a single score. This would support care planning, with interventions selected in response to specific risk factors.

TABLE 34 Minimum Data Set items to be incorporated into the Risk Assessment Framework

Risk factor	Mobility
Screening stage	
Mobility	(a) Does the patient walk without help? (b) Does the patient change position?
PU status	(a) Current PU (category 1 or above) (b) Reported history of PU
Full assessment stage	
Immobility items to incorporate the frequency of independent movement, e.g.	(a) Doesn't move (b) Moves occasionally (c) Moves frequently
Immobility items to incorporate the magnitude of independent movement, e.g.	(a) Doesn't move (b) Slight position changes (c) Major position changes
Immobility items to incorporate general, clinically relevant descriptions of movement, e.g.	(a) Bedfast (b) Chairfast (c) Walks with assistance
Sensory perception	(a) Does the patient feel and respond appropriately to discomfort from pressure
PU (existing and previous PU)	(a) Category of PU (where possible for previous PU) (b) Site of PU (c) Presence of scar tissue (for previous PU)
General skin status	(a) Confirmation of vulnerable skin, e.g. dryness, paper thin and redness (b) Pressure area skin site
Perfusion	(a) Conditions affecting central circulation, e.g. shock, heart failure and hypotension (b) Conditions affecting peripheral circulation, e.g. peripheral vascular/arterial disease
Diabetes	(a) Presence of diabetes
Moisture Frequency	(a) Presence of moisture due to perspiration, urine, faeces or exudate (b) Frequent (one or two times a day) (c) Constant
Nutrition	(a) Unplanned weight loss (b) Poor nutritional intake (c) Low BMI (d) High BMI

PU, pressure ulcer.

Draft Risk Assessment Framework

Using the results from cycle 1 and 2 of the study, an initial draft of the Risk Assessment Framework was produced (see *Appendix 23*) incorporating the screening and full assessment stage and decision pathways of the assessment process. This underwent further graphic design prior to pre-testing.

Phase 3: development of a new conceptual framework and theoretical causal pathway for pressure ulcer development

The *Aims and objectives, Methods* and *Results* sections are largely reproduced, with amendments, from Coleman S, Nixon J, Keen J, Wilson L, McGinnis E, Dealey C, *et al*. A new pressure ulcer conceptual framework, *J Adv Nurs*, with permission from John Wiley & Sons.[187]

By bringing together the relevant fields of enquiry and clarifying key risk factors for pressure ulcer development, the consensus study provided an opportunity to undertake an additional piece of work to review and enhance the pressure ulcer conceptual framework.[1] This was to bridge the gap between the epidemiological, physiological and biomechanical evidence and enhance our understanding of the role of individual risk factors in pressure ulcer development. This was not part of the programme outline initially but emerged as an additional output of the work.

Aim and objectives

The aim was to develop a new pressure ulcer conceptual framework. Specific objectives were to:

1. review and update the biomechanical elements of the NPUAP/EPUAP 2009 conceptual framework
2. develop a theoretical causal pathway for pressure ulcer development
3. map risk factors identified in the consensus study to the updated conceptual framework.

Methods

The expert group reconvened in an additional facilitated meeting which was planned so that members had access to the outcomes of the consensus study, the evidence of the systematic review[46] and risk factor/causal factor terminology before the face-to-face meeting. Familiarity with the risk factor/causal factor terminology allowed us to explore the role of the risk factors in the pressure ulcer causal pathway. This was facilitated by consideration of definitions from Brotman and colleagues:[188]

- risk factor – a variable with a significant statistical association with a clinical outcome
- independent risk factor – a risk factor that retains its statistical association with the outcome when other established risk factors for the outcome are included in a statistical model
- non-independent risk factor – a risk factor that loses its statistical association with the outcome when other established risk factors for the outcome are included in a statistical model.

Brotman and colleagues[188] suggest that a causal factor is a risk factor that has a causal relationship with a clinical outcome and is defined experimentally (known to affect outcome) rather than statistically. They make a distinction between direct and indirect causal factors:

- Direct causal factor – directly impacts the outcome (or the likelihood of the outcome).
- Indirect causal factor – impacts the outcome (or affects its likelihood of occurrence) by changing a direct causal factor. If the direct causal factor is prevented from changing then changes in the outcome will not be produced.

In our work we further categorised indirect causal factors into key indirect causal factors (for which the epidemiological/wider scientific evidence and/or clinical resonance was stronger) and other indirect causal factors. Meeting discussions were audio recorded and transcribed, allowing key themes to be identified.

Data analysis

In addition to considering the outcomes of the consensus study (see *Phase 2: consensus study*), the researcher (SC) listened to the audio tapes of the conceptual framework expert group meeting discussions and read the associated transcripts in total to ensure completeness. The analysis allowed the researcher (SC) to draft the new pressure ulcer conceptual framework and theoretical causal pathway, which was circulated to the expert group by e-mail to ensure content validity.

Results

The expert group discussions led to amendments to the existing NPUAP/EPUAP conceptual framework,[1] as illustrated in *Figure 15*. Most notably, it was recognised that, although mechanical properties of the tissues and geometry (morphology) of the tissues and underlying bones impact on the internal strains and stresses (as an example, subjects who are either very emaciated or very obese will have enhanced strains and stresses within the soft tissues), their impact was considered to be more relevant to the susceptibility of the individual (i.e. impacting on the damage threshold). Furthermore, transport (perfusion and lymphatic drainage) also impacts on the damage threshold of the individual and this would also be affected by temperature in terms of vasodilation/vasoconstriction, thereby affecting tissue perfusion. The underlying physiology of an individual will also have an impact on his or her repair capacity and this was an important consideration that was captured in the amended conceptual framework (see *Figure 15*).

The theoretical schema of a proposed causal pathway for pressure ulcer development detailing the direct, key indirect and other potential indirect causal factors is illustrated in *Figure 16*. *Table 35* shows the mapping of the direct causal factors and key indirect causal factors against the key components of the enhanced 2009 NPUAP/EPUAP conceptual framework. Although it was recognised that the presence and weighting of specific risk factors may vary in relation to the anatomical site of the pressure ulcer, it was not possible to delineate the evidence to skin site-level risk factors.

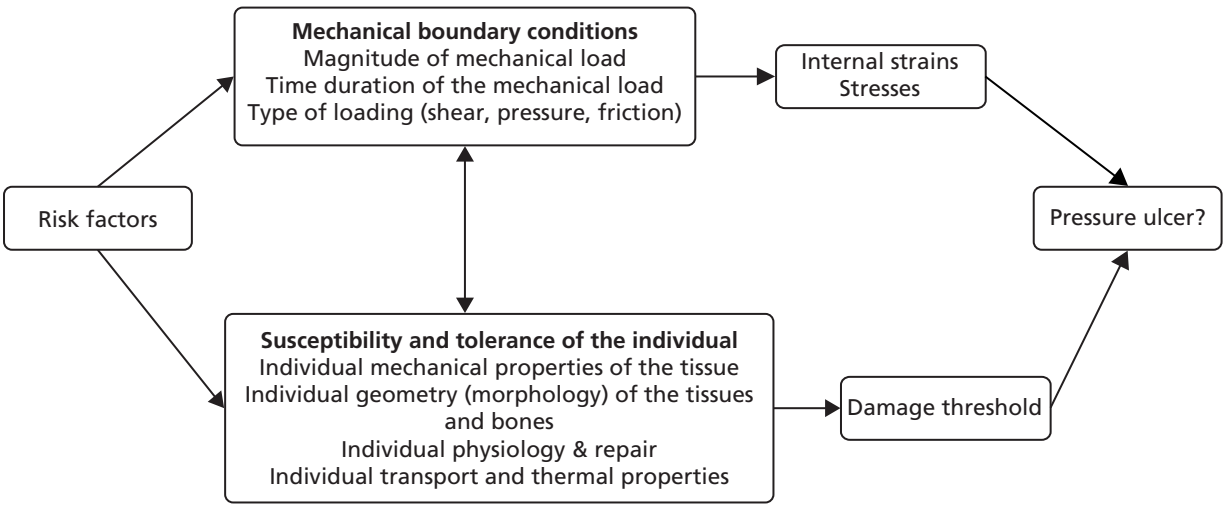

FIGURE 15 Enhanced NPUAP/EPUAP (2009) factors that influence susceptibility for pressure ulcer development. Reproduced from Coleman, Nixon, Keen, Wilson, McGinnis, Dealey *et al*. A new pressure ulcer conceptual framework. *J Adv Nurs* 2014;**70**:2222–34.[187] © 2014 The Authors. *Journal of Advanced Nursing* Published by John Wiley & Sons Ltd. This is an open access article under the terms of the TODO: clickthrough URLCreative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

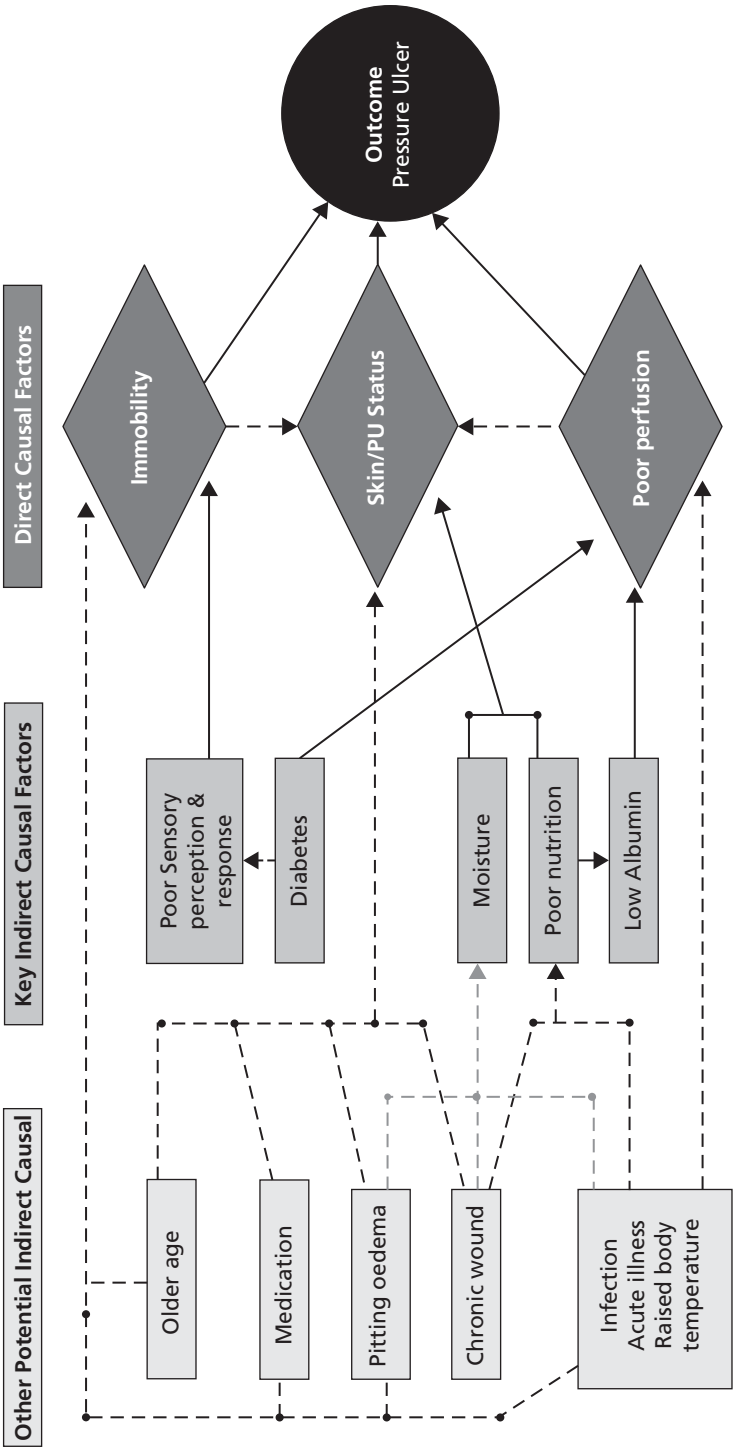

FIGURE 16 Theoretical schema of proposed causal pathway for pressure ulcer development. PU, pressure ulcer. The solid arrows show the causal relationships between the key indirect causal factors, direct causal factors and the outcome. Broken arrows show the causal relationships between other potential indirect causal factors and key indirect causal factors and between direct causal factors. Broken arrows also demonstrate inter-relationships between direct causal factors and indirect causal factors. Reproduced from Coleman, Nixon, Keen, Wilson, McGinnis, Dealey *et al.* A new pressure ulcer conceptual framework. *J Adv Nurs* 2014;**70**:2222–34.[187] © 2014 The Authors. *Journal of Advanced Nursing* Published by John Wiley & Sons Ltd. This is an open access article under the terms of the TODO: clickthrough URLCreative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

TABLE 35 Mapping of direct causal and key indirect causal factors to the conceptual framework

Risk factor	Mechanical boundary conditions: type of loading (shear, pressure, friction) and magnitude and duration of mechanical load	Individual geometry (morphology) of the tissue and bones	Individual mechanical property of the tissues	Individual transport and thermal properties	Individual physiology and repair
Immobility	✗				
Skin/PU status		✗	✗	✗	✗
Poor perfusion				✗	✗
Poor nutrition		(✗) in extreme cases	(✗) in extreme cases	✗	✗
Moisture	✗		✗		
Poor sensory perception and response	(✗) through immobility				
Diabetes	(✗) through sensory perception			(✗) through perfusion	
Low albumin level				(✗) through perfusion	

PU, pressure ulcer.

Direct causal factors

Three characteristics were classified as direct causal factors: immobility, skin/ulcer status and perfusion. Immobility is a necessary condition for pressure ulcer development and is therefore considered a direct causal factor (see *Figure 16*); through its impact on mechanical boundary conditions (see *Table 35*) it directly impacts the outcome (or the likelihood of the outcome). Of note is that friction and shear is not specified as a patient characteristic but rather as a characteristic of the mechanical boundary condition (see *Table 35*).

Identifying whether skin/ulcer status (incorporating existing and previous pressure ulcers and general skin status) and poor perfusion represent a direct or indirect risk factor is less straightforward. It could be assumed that they are indirect factors as without some degree of immobility a pressure ulcer would not develop. However, this is not in keeping with the definitions of causal factors and oversimplifies the complex interplay of factors required to lead to tissue damage. There is strong epidemiological/wider scientific evidence that poor perfusion and skin/ulcer status reduce patients' tolerance to pressure and increase the likelihood of pressure ulcer development, suggesting that they are direct causal factors, and this may explain why some immobile patients develop pressure ulcers whereas others do not.

Further insight was gained by mapping skin/ulcer status and poor perfusion to the conceptual framework; it was apparent that they were clearly implicated in the susceptibility and tolerance aspect of the framework (see *Table 35*). Skin/ulcer status mapped to the individual geometry (morphology) of the tissue and bones, the mechanical property of the tissues, the transport and thermal properties and the physiology and repair aspects of the framework. Perfusion mapped to the individual transport and thermal properties and the physiology and repair elements of the framework and is related to factors that impair circulation. Within the

expert group it was recognised that oxygen-carrying capacity was important in maintaining healthy tissues, although it was also recognised that other factors such as the delivery of nutrients and waste removal were important, and at present it is difficult to determine the most important factors relating to perfusion. Further confirmatory research is needed to more clearly ascertain the aetiological mechanisms of importance.

Key indirect causal factors

Moisture, sensory perception, diabetes, low albumin level and poor nutrition were considered key indirect causal factors as they impact the outcome (or affect its likelihood of occurrence) by changing a direct causal factor (see *Figure 16*).

Other potential indirect causal factors

The theoretical conceptual schema (see *Figure 16*) was further developed to include other indirect causal factors to illustrate the potential relationships and the impact of diverse factors that may be involved in the causal pathway. However, it is recognised that the inter-relationships among potential and key indirect causal factors are complex and require further elucidation. Other potential indirect causal factors include those with weak or limited epidemiological/wider scientific evidence but which are thought to impact on key indirect and direct causal factors. These include age, medication and pitting oedema as well as other factors relating to general health status including infection, acute illness, raised body temperature and chronic wound.

New pressure ulcer conceptual framework

Having considered the causal pathway for pressure ulcer development (see *Figure 16*) and mapped the direct and key indirect causal factors for ulcer development against the components of the enhanced conceptual framework (see *Table 35*), a new conceptual framework is proposed that enables the epidemiological evidence to be linked to the conceptual framework (*Figure 17*). The new framework shows that there is a relationship between the mechanical boundary conditions and the susceptibility and tolerance of the individual. The risk factors that impact the mechanical boundary conditions and the susceptibility and tolerance of the individual are detailed in the framework and are based on the direct causal factors of immobility, skin/ulcer status and poor perfusion as well as on the key indirect causal factors of poor sensory perception and response, diabetes, poor nutrition, moisture and low albumin level.

For simplicity, the risk factors are represented under the elements that they predominantly affect (either mechanical boundary conditions or susceptibility and tolerance of the individual), but the broken line running under the risk factors indicates that some risk factors may have an effect on both sides of the framework, which is more clearly articulated in the theoretical schema (see *Figure 16*) and risk factor mapping (see *Table 35*). The absence of risk factors on either the individual susceptibility and tolerance or the mechanical boundary conditions side of the framework would affect the likelihood of pressure ulcer development [i.e. a patient with good perfusion may be able to tolerate higher levels of immobility (without developing a pressure ulcer) than a patient with poor perfusion].

Phase 4: design and pre-testing of the Risk Assessment Framework (incorporating the risk factor Minimum Data Set)

The consensus study identified the risk factors and assessment items and suggested a structure for the Risk Assessment Framework (incorporating the risk factor Minimum Data Set). With these elements agreed we engaged the support of a graphic designer (see *Acknowledgements*) to develop the new Risk Assessment Framework in a way that would facilitate ease of use. This incorporated the use of colour to aid clinical decision-making. To ensure that clinicians/nurses understood and were able to use the Risk Assessment Framework, the next study of the work package was undertaken – pre-testing of the Risk Assessment Framework (see *Appendix 24* for study protocol).

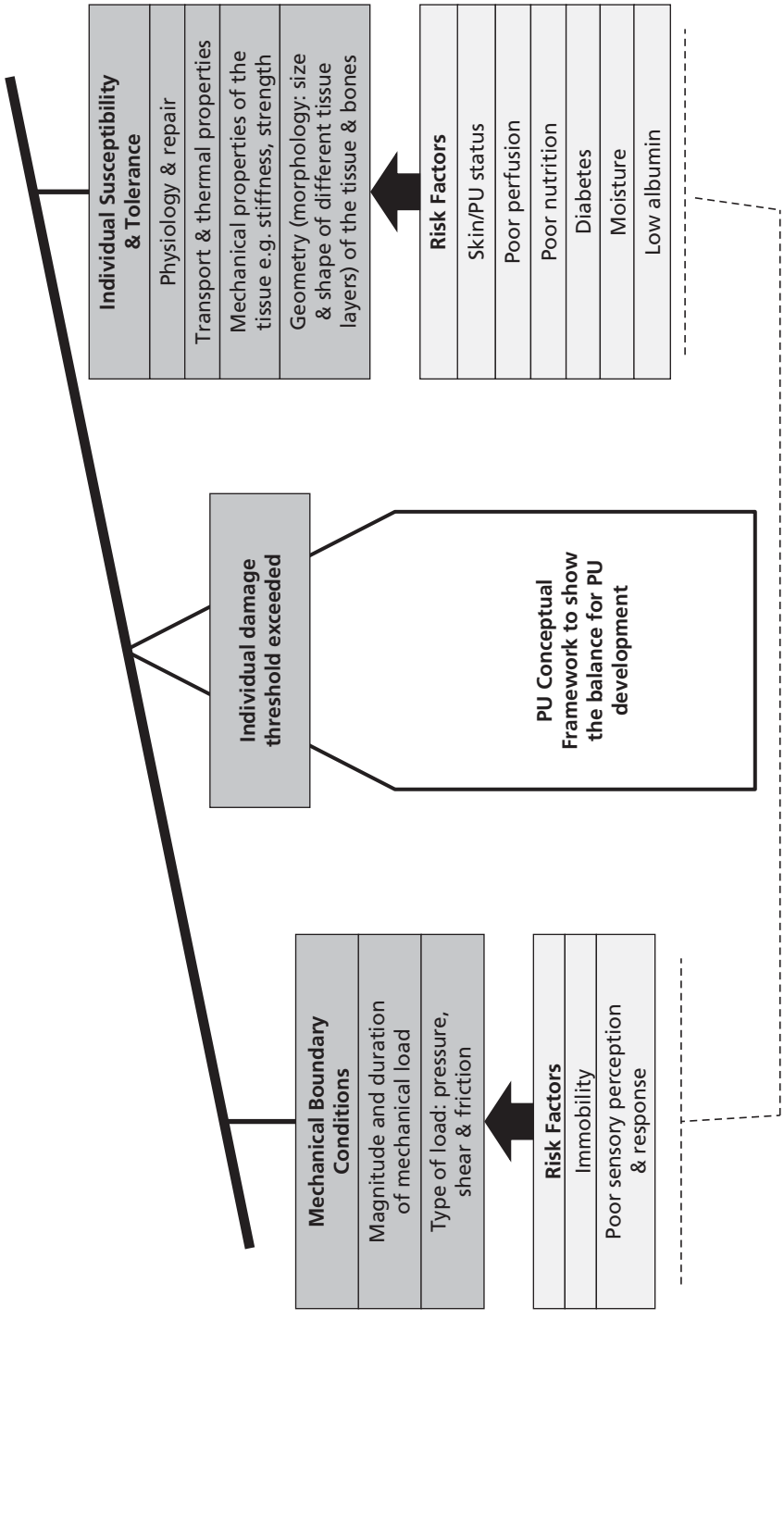

FIGURE 17 New pressure ulcer conceptual framework. PU, pressure ulcer. Reproduced from Coleman, Nixon, Keen, Wilson, McGinnis, Dealey *et al.* A new pressure ulcer conceptual framework. *J Adv Nurs* 2014;**70**:2222–34.[187] © 2014 The Authors. *Journal of Advanced Nursing* Published by John Wiley & Sons Ltd. This is an open access article under the terms of the TODO: clickthrough URLCreative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

Study aim

The aim was to assess and improve the acceptability, usability, format, design, clarity, comprehension, language and data completeness of the draft Risk Assessment Framework (incorporating the risk factor Minimum Data Set) with clinical nurses.

Methods

Cognitive pre-testing methods were used to evaluate how clinical nurses interpreted questions, response categories and instructions while using the draft Risk Assessment Framework.[189] This was conducted over three pre-test sessions and incorporated three focus groups and 12 'think out loud' interviews, estimated as the number required for data saturation. It was anticipated that focus groups with nurses in similar roles (e.g. staff nurses, senior nurses) would facilitate greater understanding of the usability of the Risk Assessment Framework, allowing group members to 'spark ideas off one another', which might lead to greater disclosure.[190]

In addition, one-to-one think out loud interviews[191] were undertaken to allow the researcher (SC) to identify specific problems with the risk assessment tool that would be amenable to resolution by modification. The study was conducted to allow analysis of and adjustment to the Risk Assessment Framework to be undertaken between pre-test sessions so that three different versions of the tool could be pre-tested and improvements made in an interative process.

Participants

For the pre-test we recruited nurses from a large acute teaching hopsital trust, a district general hospital and two primary care trusts. Purposive sampling was undertaken to ensure that tissue viability nurses, staff nurses and sisters from hospital and community settings were recruited from each of the four participating sites. Participants included those who had an interest in tissue viability (e.g. a link nurse or member of a local pressure ulcer or wound care working group). The study was approved by the University of Leeds School of Healthcare Research Ethics Committee. Informed consent was obtained prior to participation in the study (see *Appendices 25* and *26* for the patient information leaflet and consent form).

Data collection

The three facilitated pre-test sessions were undertaken away from the clinical environment and involved 8–12 nurses from the four participating sites, who were grouped by job role (staff nurse, sister/charge nurse and tissue viability nurse specialist/research nurse) to facilitate openness, as the use of heterogeneous groups can lead to inhibition in raising issues that do not seem to be shared by others.[190] This was thought to be particularly important for this group as a hierarchy might have stifled disclosure (e.g. a staff nurse might not want to disagree with the views of his/her ward sister). Having nurses from different centres minimised familiarity, which can lead to participants relying on 'taken for granted' assumptions.[190] At the pre-test session, the nurses were trained in how to use the Risk Assessment Framework and were then randomly allocated to either a focus group or a one-to-one think out loud interview.

Training involved a short presentation and demonstration on how to use the draft Risk Assessment Framework with a simulated patient. Each nurse then completed the draft Risk Assessment Framework using case studies and vignettes (see *Appendix 27*) that were accompanied by photographs of pressure areas and ulcers. The vignettes were appropriate to the nurses' area of practice (i.e. community nurses used vignettes of community patients). The vignettes were co-developed by the project lead, the project team and members of PURSUN UK to ensure that they were realistic and clinically relevant. Nurses were encouraged to ask questions throughout the training session.

The sessions were planned to ensure that four to eight nurses[192] per pre-test were assigned to the focus group. Each was asked to complete the Risk Assessment Framework again, using three case studies relevant to their area of practice. Nurse participants were encouraged to highlight any areas of the Risk Assessment Framework form that they found confusing. A co-facilitator assessed data completeness and

listed areas where data items were not completed or were not completed as required, as well as areas noted by the nurses as confusing. The focus group meeting then convened to discuss the use of the Risk Assessment Framework. The meeting was moderated by two facilitators and audio recorded. The moderator promoted group interaction and guided discussions using a topic guide (see *Appendix 28*), which considered the usability of the Risk Assessment Framework and any areas of confusion regarding its use. This was informed by the data completeness assessment.

Up to four nurses from each session were assigned to the one-to-one think out loud interviews. A topic guide (see *Appendix 29*) was used and the researcher first guided the nurses though the think out loud technique. Once the nurse were content with the approach, they were asked to complete the Risk Assessment Framework again in the presence of the researcher using three vignette case studies appropriate to their area of practice. The researcher encouraged the nurses to vocalise their thoughts as they completed the Risk Assessment Framework. This allowed specific issues relating to difficulty in interpreting items or confusion about aspects of the Risk Assessment Framework to be identified. The interviews were audio recorded.

Analysis

Data completeness of the Risk Assessment Framework forms was undertaken by calculating the percentage of item-level missing data, the percentage of decision pathways allocated and the percentage of item-level missing data for those for whom a decision pathway was allocated. The appropriateness of the allocated decision pathway was also assessed based on the decision rules of the Risk Assessment Framework and the item responses for each assessment.

The focus group meetings and the think out loud interviews were audiotaped and transcribed. The researcher listened to the audio tapes and read the transcripts to ensure accuracy and to ensure that a good overview of the discussions had been achieved. The data were then coded, which was directed by the risk factor items of the Risk Assessment Framework, using a directed content analysis approach.[183] The emphasis was on identifying themes across the focus groups and think out loud interviews that impacted on the application of the Risk Assessment Framework in clinical practice. A summary report of each meeting was reviewed by the facilitators to ensure that it reflected the discussions that had taken place. The report was considered by a working group (consisting of clinical and academic leaders in the pressure ulcer field) and adjustments were made to the draft Risk Assessment Framework, which was pre-tested at the subsequent session in an iterative process. Following pre-testing, the Risk Assessment Framework was also reviewed by PURSUN UK and the consensus study expert group.

Results

The pre-test sessions were well attended by 34 nurses from acute ($n = 16$) and community ($n = 18$) settings. Over the three pre-test sessions, 101 Risk Assessment Framework assessments were undertaken using vignette case studies by 11 tissue viability/research nurses ($n = 32$ Risk Assessment Framework assessments), 12 staff nurses ($n = 36$ Risk Assessment Framework assessments) and 11 sisters ($n = 33$ Risk Assessment Framework assessments). At each pre-test session, four nurses undertook the think out loud interviews and seven or eight nurses attended the focus groups. *Table 36* details the level of data completion for each pre-test session, which can be seen to improve as the Risk Assessment Framework was amended over the three pre-test sessions.

An inappropriate decision pathway was allocated when an assessment detailed the presence of a ulcer and the case–study patient should have been allocated to the 'pressure ulcer category 1 or above or scarring' pathway but was allocated to the 'at-risk' pathway. Uncertainty about the appropriateness of the allocated pathway related to missing data, for example a patient was allocated to the 'not currently at risk' pathway but the skin assessment items were not fully completed and hence there was a possibility that a higher pathway was appropriate.

TABLE 36 Item-level completion for assessments that concluded at step 1 and for assessments that included steps 1 and 2

RAF assessment concluding at step 1 screening	Pre-test 1: number of related items requiring completion PA	Pre-test 1 (TVNs/RNs): items completed, % (*n*/*N*)	Pre-test 2: number of related items requiring completion PA	Pre-test 2 (staff nurses): items completed, % (*n*/*N*)	Pre-test 3: number of related items requiring completion PA	Pre-test 3 (sisters): items completed, % (*n*/*N*)
Mobility	4	100 (24/24)	At least 1 of 4	100.0 (10/10)	At least 1 of 4	100.0 (8/8)
Skin/PU status	2	66.7 (8/12)	At least 1 of 4	90.0 (9/10)	At least 1 of 4	100.0 (8/8)
Decision pathway allocated	1	0 (0/6)	1	100.0 (10/10)	1	87.5 (7/8)
Number of RAF assessments concluding at step 1		76.2 (32/42)		96.7 (29/30)		95.8 (23/24)
RAF assessment including step 1 (screening) and step 2 (full assessment)	**Pre-test 1: number of related items requiring completion PA**	**Pre-test 1 (TVNs/RNs): items completed, % (*n*/*N*)**	**Pre-test 2: number of related items requiring completion PA**	**Pre-test 2 (staff nurses): items completed, % (*n*/*N*)**	**Pre-test 3: number of related items requiring completion PA**	**Pre-test 3 (sisters): items completed, % (*n*/*N*)**
Mobility (first stage)	4	93.3 (97/104)	At least 1 of 4	96.2 (25/26)	At least 1 of 4	100.0 (25/25)
Skin/PU status (first stage)	2	98.1 (51/52)	AA	100.0 (3/3)	AA	100.0 (1/1)
Movement matrix	1	100 (26/26)	1	100.0 (26/26)	1	96.0 (24/25)
Sensory perception	1	96.2 (25/26)	1 of 2	100.0 (26/26)	1 of 2	100.0 (25/25)
Current DSA – listed sites	15	71.5 (279/390)	13	75.4 (255/338)	13	97.2 (316/325)
Current DSA – other sites	AA	0 (0/0)	AA	50.0 (1/2)	AA	0 (0/0)
Current PU	AA	84.2 (16/19)	AA	83.3 (20/24)	AA	80.0 (20/25)
Previous PU history	AA	75.0 (9/12)	AA	77.8 (7/9)	1 of 2 (if yes 3, AA)	85.3 (29/34)
Scarring	2	55.8 (29/52)	AA	100.0 (1/1)	AA	100.0 (1/1)
Perfusion	2	92.3 (48/52)	At least 1 of 3	73.1 (19/26)	At least 1 of 3	100.0 (25/25)
Nutrition	4	76.9 (80/104)	At least 1 of 5	100.0 (26/26)	At least 1 of 5	100.0 (25/25)

RAF assessment including step 1 (screening) and step 2 (full assessment)	Pre-test 1: number of related items requiring completion PA	Pre-test 1 (TVNs/RNs): items completed, % (*n*/*N*)	Pre-test 2: number of related items requiring completion PA	Pre-test 2 (staff nurses): items completed, % (*n*/*N*)	Pre-test 3: number of related items requiring completion PA	Pre-test 3 (sisters): items completed, % (*n*/*N*)
Moisture	1 (if yes 2 as applicable)	74.1 (40/54)	1 of 3	84.6 (22/26)	1 of 3	100.0 (25/25)
Diabetes	1	100.0 (26/26)	As applicable	100.0 (5/5)	1 of 2	100.0 (25/25)
Decision pathway allocated	1 of 3	53.8 (14/26)	1 of 3	96.2 (25/26)	1 of 3	100.0 (25/25)
Total RAF assessments including steps 1 and 2		78.5 (740/943)		81.7 (461/564)		96.6 (566/586)
Overall total[a]		78.4 (772/985)		82.5 (490/594)		96.6 (589/610)
Overall total[b]		83.7 (417/498)		84.4 (481/570)		96.7 (587/607)

AA, as applicable; DSA, detailed skin assessment; PA, per assessment; PU, pressure ulcer; RAF, Risk Assessment Framework; RN, research nurse; TVN, tissue viability nurse.
a Assessment concluding at step 1 and assessment including steps 1 and 2.
b Item-level completion where decision pathway allocated.

Figure 18 illustrates how the levels of missing data decreased over the three pre-test sessions overall and when a decision pathway was allocated. *Figure 19* illustrates how the number of decision pathways allocated increased notably from the first to the second pre-test. *Table 37* presents the appropriateness of the decision pathways allocated according to the decision rules of the Risk Assessment Framework and the item responses for each assessment.

Changes made to the Risk Assessment Framework between pre-test sessions in response to the analysis of data completeness, think out loud interviews and focus groups are summarised in *Figure 20* and related to three main areas: flow and format, decision support and wording of specific items. An example of the changes made to these main areas between pre-test sessions is shown in *Figures 21–23* in relation to step 1 of the assessment. It should be acknowledged that, following these changes, some nurses still completed the step 1 skin/ulcer

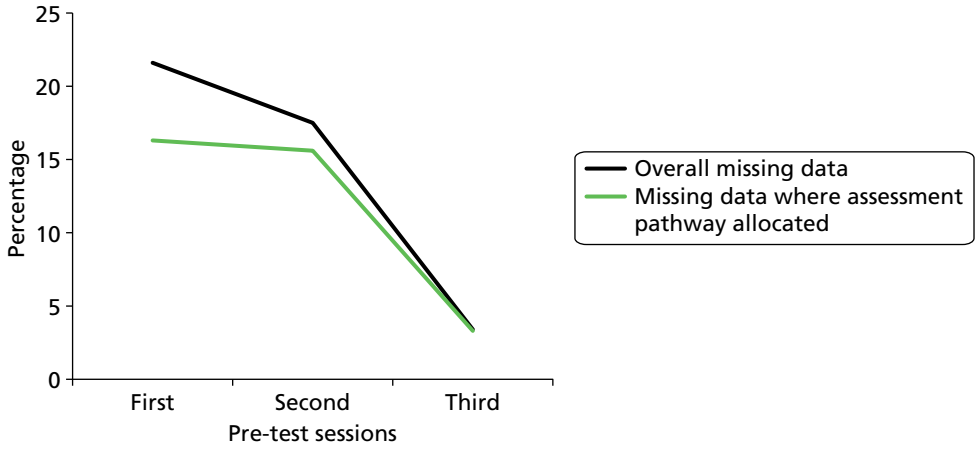

FIGURE 18 Percentage of missing data at each pre-test session.

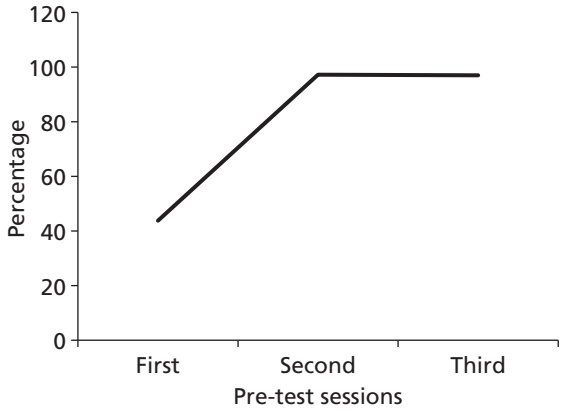

FIGURE 19 Percentage of decision pathways allocated at each pre-test session.

TABLE 37 Appropriate decision pathway allocation

Decision pathway allocation	Pre-test session 1 (TVNs/RNs), % (*n*/*N*)	Pre-test session 2 (staff nurse), % (*n*/*N*)	Pre-test session 3 (Sisters), % (*n*/*N*)
Appropriate pathway allocation	78.6 (11/14)	91.4 (32/35)	90.6 (29/32)
Inappropriate pathway allocation	7.1 (1/14)		
Pathway allocated but some uncertainty in appropriateness because of missing data items	14.3 (2/14)	8.6 (3/35)	9.4 (3/32)

RN research nurse; TVN, tissue viability nurse.

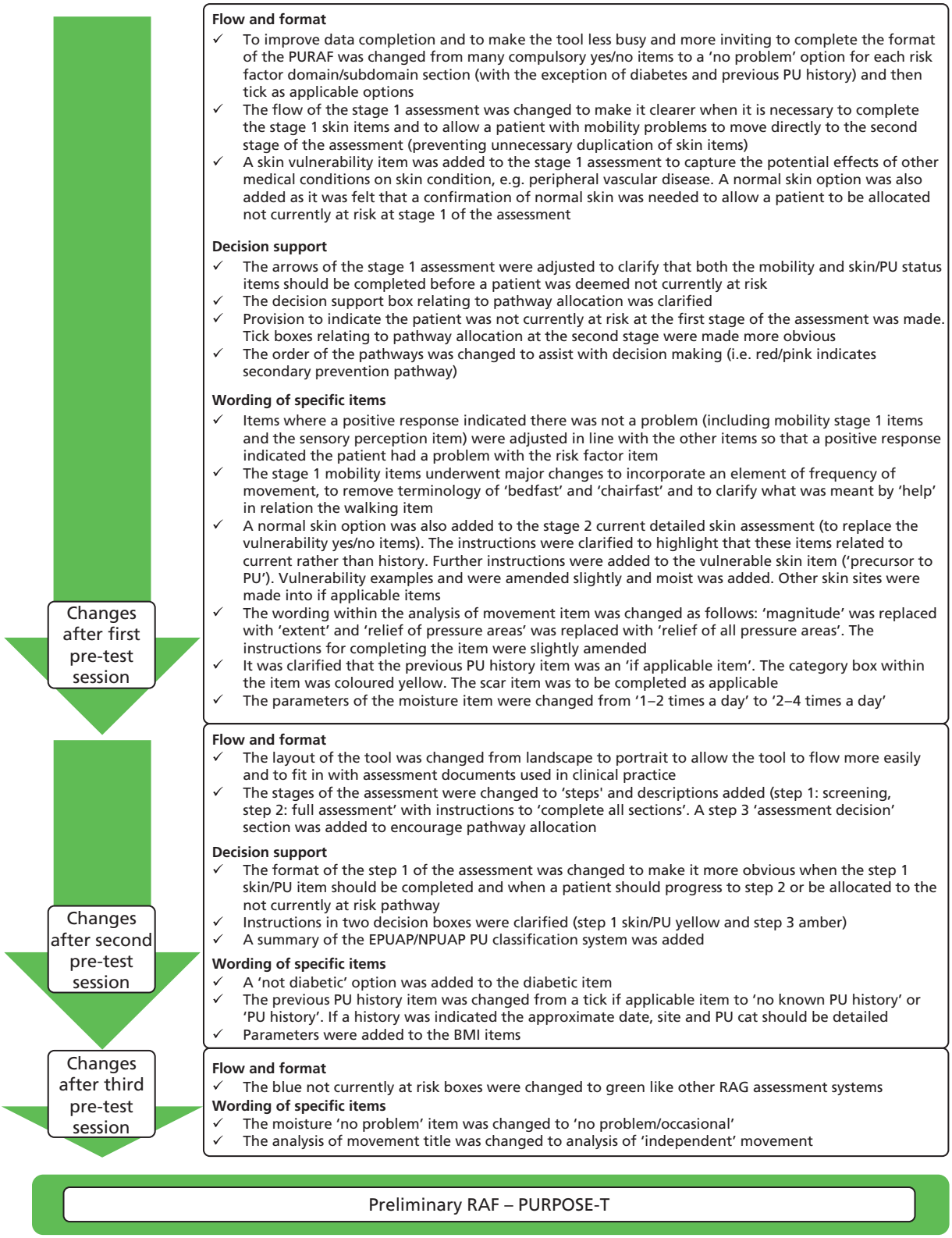

FIGURE 20 Changes to the Risk Assessment Framework following each pre-test session. PU, pressure ulcer; PURAF, Pressure Ulcer Risk Assessment Framework; RAG, red, amber, green.

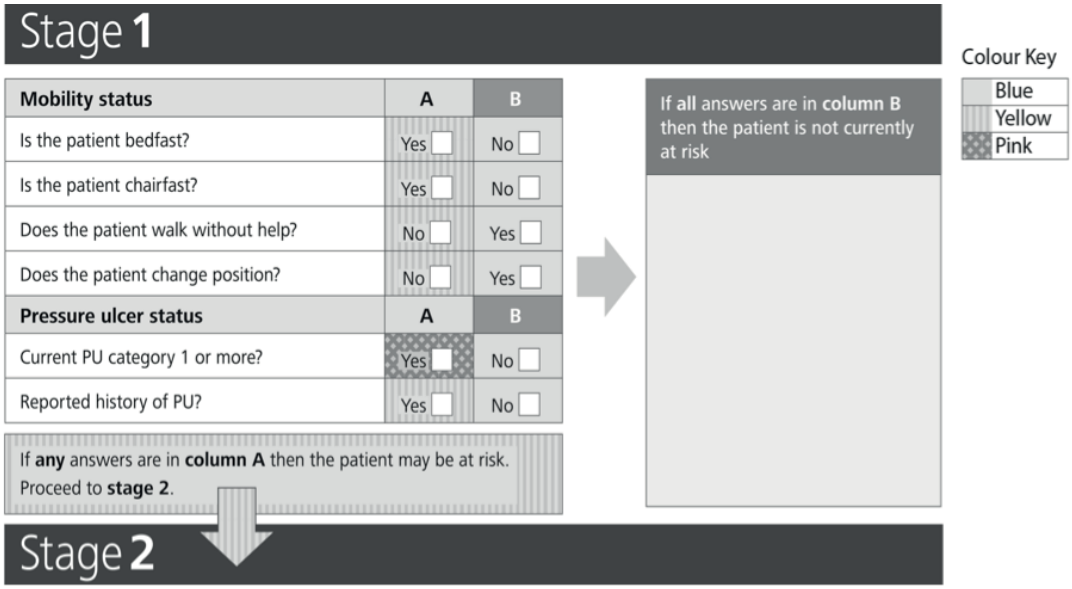

FIGURE 21 Pre-test session 1 draft Risk Assessment Framework. Please note that the Risk Assessment Framework incorporates the use of colour. These examples have been adapted with the colour key provided.

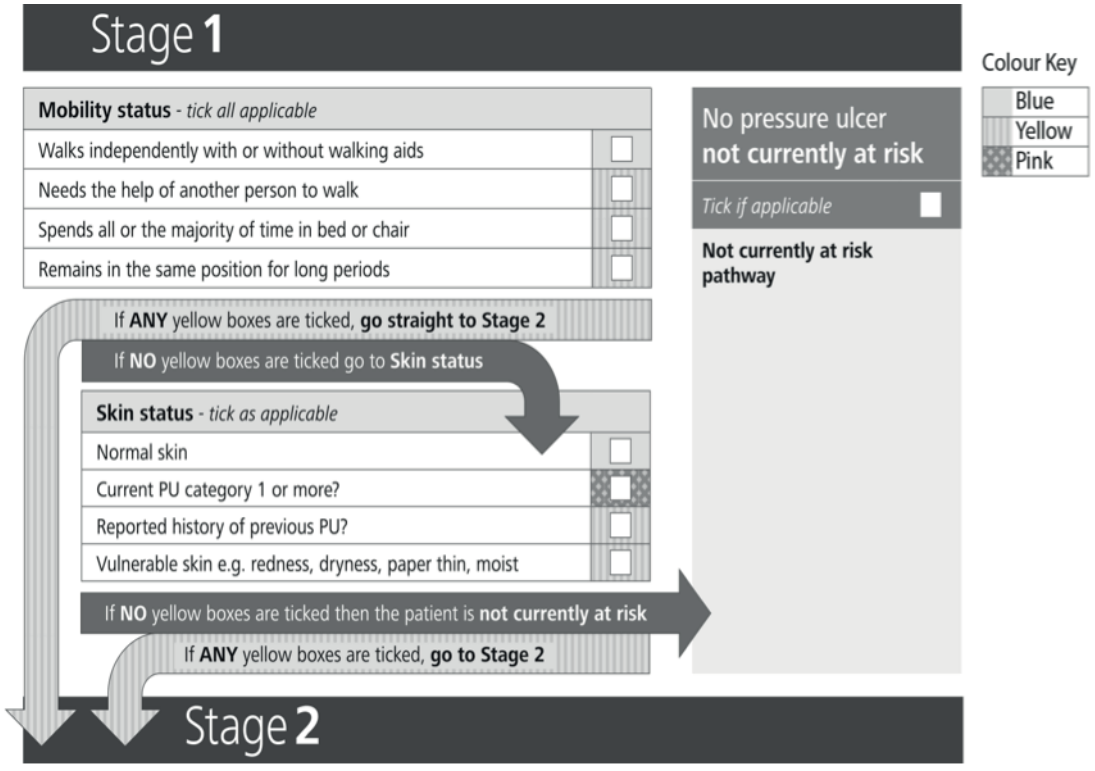

FIGURE 22 Pre-test session 2 draft Risk Assessment Framework. Please note that the Risk Assessment Framework incorporates the use of colour. These examples have been adapted with the colour key provided.

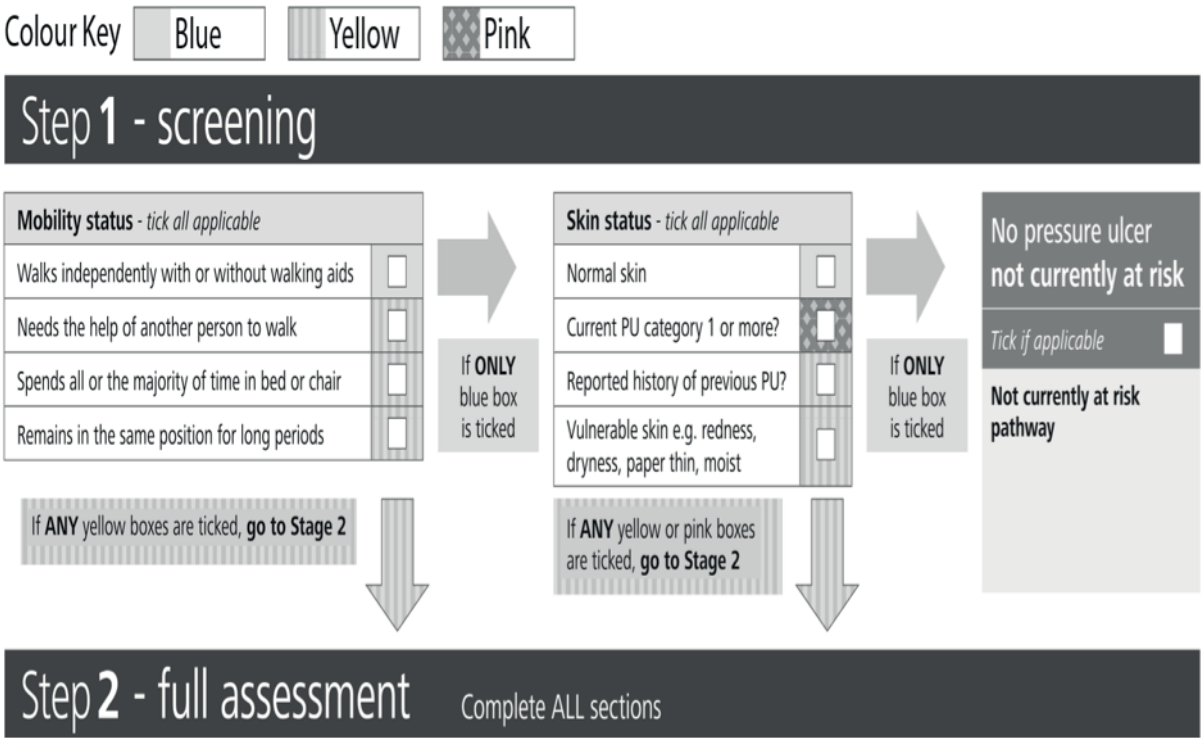

FIGURE 23 Pre-test session 3 draft Risk Assessment Framework. Please note that the Risk Assessment Framework incorporates the use of colour. These examples have been adapted with the colour key provided.

items despite not needing to. This could be related to the use of case studies in the pre-test sessions in which information on skin/ulcer status was readily available, whereas in clinical practice this information may be less obvious.

Other notable changes made over the course of the pre-test session relate to the move from landscape to portrait orientation to improve the flow of the tool and the development of specific items (e.g. the terminology relating to 'bedfast' and 'chairfast' in the step 1 mobility items was found to be confusing and there was a need to incorporate an element of frequency to the items, which were subsequently amended and tested at the next session). The think out loud participants from the first pre-test also highlighted that items for which a positive response indicated that the patient did not have a problem were confusing. This related to step 1 mobility items and the step 2 sensory perception item and changes were made to the Risk Assessment Framework used at subsequent sessions.

The first pre-test focus group felt that there should be some provision within step 1 of the Risk Assessment Framework to enable nurses to use their clinical judgement in terms of other significant risk factors (which may be exceptions to the rule) that they should take into account when considering if a patient should progress to the more detailed step 2 assessment. This could relate to the severity of a risk factor (e.g. terminally ill patients, severe diabetes, perfusion problems and severe nutritional problems). Having 'other items' at step 1 was considered by the working group but there was concern that the screening stage could become too large. Taking into account the causal pathway for pressure ulcer development, it was decided that a 'vulnerable skin' item would be included instead to focus the assessment on the potential impact that other medical conditions might have on the skin, rather than on the presence or absence of many different conditions.

The data completeness assessment (see *Table 36* and *Figure 18*) showed poor decision pathway allocation in the first pre-test. The corresponding focus group discussions highlighted confusion over where to indicate the pathway allocation; some nurses had attempted to indicate a pathway on the form although they were clearly unsure of where to do this. This alerted us to a significant omission and lack of clarity

within the Risk Assessment Framework and the need to include a response box within the 'not currently at risk' pathway at the first stage of the assessment and to make the pathway allocation tick boxes at stage 2 of the assessment more obvious. In addition, the think out loud interviews in the first pre-test session highlighted an issue relating to the ordering of the decision pathway boxes in the first draft Risk Assessment Framework, that is, the first pathway (left) being the blue 'not currently at risk pathway', the second pathway (middle) being the orange primary prevention pathway and the third pathway (right) being the red secondary prevention/treatment pathway, and the resultant possibility of ticking the primary prevention pathway before getting to the secondary prevention/treatment pathway. It was suggested that, as 'red trumps orange', the boxes should be reordered so that the red one was first, and this was undertaken for the second pre-test (see *Figures 21–23*).

The review of the Risk Assessment Framework by PURSUN UK and the expert group (following pre-testing) led to a final change to the Risk Assessment Framework. Although members of PURSUN UK felt that the Risk Assessment Framework was clear and understandable, they raised concern about the wording of the sensory perception item; this related to the 'ability to feel and respond' aspect of the item. The group agreed that the patient might be able to fulfil only one of these requirements, which should be considered a problem, but the wording suggested that it would be a problem only if the patient could not do both. They felt that the terminology should be 'feel and/or respond'. This led to the wording of the sensory perception item being reconsidered at the subsequent expert group meeting and amendments being made.

The pre-test facilitated the development of the preliminary Risk Assessment Framework (see *Appendix 30*), which was easily understood by clinical nurses. The Risk Assessment Framework was subsequently named the PURPOSE-T and will be further evaluated in clinical practice.

Phase 5: clinical evaluation of the PURPOSE-T (Risk Assessment Framework incorporating the risk factor Minimum Data Set)

To enable the provisional Risk Assessment Framework (PURPOSE-T) to be used with confidence in clinical practice, the fifth phase of the work package examined the fundamental properties of the instrument. This involved a field test to assess its reliability, convergent validity and clinical usabilty (see *Appendix 31* for the study protocol).

Aims

The aims of field test 1 were to assess the:

- data completeness and clinical usability of the PURPOSE-T
- inter-rater and test–retest reliability of the PURPOSE-T
- convergent validity and known groups validity of the PURPOSE-T.

Methods

Design

The PURPOSE-T was evaluated through field testing using observational descriptive methods. Hospital inpatients and community nursing patients were invited to participate. Demographic characteristics were collected and individual pressure ulcer risk was assessed for all patients. Paired assessments were undertaken simultaneously using the PURPOSE-T, one by a ward/community nurse and one by an expert nurse, with each nurse remaining blind to the corresponding assessment. A blinded retest was undertaken by the same expert nurse at a follow-up visit.

In addition, the expert nurses involved in data collection kept field notes of their experience of using the PURPOSE-T in clinical practice and comments from ward/community nurses during their use of the PURPOSE-T. The field notes were summarised and used to inform design amendments and issues of importance for implementation.

Description of the preliminary PURPOSE-T

The PURPOSE-T (field test version) incorporates a three-step assessment process:

- step 1 – screening assessment of mobility and skin status
- step 2 – full assessment of analysis of independent movement, sensory perception, detailed skin assessment, previous pressure ulcer history, perfusion, nutrition, moisture and diabetes
- step 3 – assessment decision of 'no pressure ulcer not currently at risk', 'no pressure ulcer but at risk' and 'pressure ulcer category 1 or above or scarring from previous pressure ulcer'.

The tool is colour coded as follows to facilitate decision-making:

- blue – 'no problem' with risk factor
- yellow – 'problem' that may impact on pressure ulcer risk
- orange – 'problem' that puts the patient at risk and requires primary prevention
- pink – patient has a pressure ulcer or scar from a previous pressure ulcer and requires secondary prevention/treatment.

The assessment decision is also colour coded using the RAG (red/amber/green) rating as follows:

- red – 'pressure ulcer category 1 or above or scarring from previous pressure ulcer'
- amber – 'no pressure ulcer but at risk'
- green – 'no pressure ulcer not currently at risk'.

At step 1 there are four mobility options with 'tick all applicable' instructions. If only the blue-coded criterion 'walks independently with or without walking aids' is ticked the instructions are to progress to step 1 skin status. If any other mobility criteria (which are all coded yellow) are ticked, the instructions are to progress to step 2 (see *Appendix 30*).

The step 1 skin status item also has four options with 'tick all applicable' instructions. If only the blue-coded 'normal skin' option is ticked the instructions are to allocate the patient to the green assessment decision – the 'no pressure ulcer not currently at risk' pathway. If any other skin status options are ticked (coded yellow and pink), the instructions are to progress to step 2 full assessment (see *Appendix 30*).

Step 2 includes assessment of the following:

- analysis of independent movement: five options, including four coded orange (with varying limitations to frequency and extent of independent movement) and one coded yellow (making major position changes frequently)
- detailed skin assessment of 13 skin sites (with the option for 'other' skin sites), with three options for each, including 'normal skin' coded blue, 'vulnerable skin' coded orange and 'pressure ulcer category 1' coded pink
- previous pressure ulcer history: two options, including 'no known pressure ulcer history' coded blue and 'pressure ulcer history' coded yellow, with presence of scar (if applicable only) coded pink
- sensory perception: two options, including 'no problem' coded blue and 'patient is unable to feel and/or respond to discomfort from pressure' coded orange
- perfusion: three options, including 'no problem' coded blue and two options coded orange: 'conditions affecting central circulation, for example shock, heart failure and hypotension' and 'conditions affecting peripheral circulation, for example peripheral vascular/arterial disease'

- nutrition: five options, including 'no problem' coded blue and four options coded yellow: 'unplanned weight loss', 'poor nutritional intake', 'low BMI' and 'high BMI'
- moisture: three options, including 'no problem/occasional' coded blue and two options coded yellow: 'frequent' and 'constant'
- diabetes: two options, including 'not diabetic' coded blue and 'diabetic' coded yellow.

Step 3 involves allocation of an assessment decision as outlined in *Table 38*.

Nurse eligibility and preparation

A nurse was defined as an expert if he or she was a member of the participating trusts' tissue viability teams (tissue viability nurse consultant/specialist/clinical research nurse). Participating expert nurses attended an initiation training day at which the PURPOSE-T was presented, the instruction manual was provided and they used the PURPOSE-T through vignettes and role play until they were confident in how to use it. In practice, all expert nurses involved in recruitment and data collection were clinical research nurses with specialist tissue viability knowledge gained through their role in other PURPOSE programme research projects.

The expert nurses in the acute sector identified a range of wards, sought verbal permission from ward managers to undertake the research and arranged a mutually convenient date with a qualified member of the ward team to undertake training and patient assessment. In the community sector the expert nurses sought volunteers from the community nursing service and arranged a mutually convenient time to undertake training and patient assessment.

All participating ward/community nurses underwent training in the use of the PURPOSE-T from the expert nurses. This included a full explanation of the PURPOSE-T and the instruction manual followed by an invitation to undertake an assessment using the same vignettes that were used by the expert group nurses in their training, so that they were familiar with the instrument. Either the ward/community nurse or the ward/community team budget received a per-patient or a per-hour payment to cover the funding required to release the ward/community nurse from usual clinical duties.

Patient eligibility

Inclusion criteria

- Age $\geq$ 18 years.
- Inpatient in the acute setting or community nursing patient in the community setting.
- Provide written informed consent/verbal witnessed consent/consultee agreement.
- Expected to be available for the PURPOSE-T retest.

TABLE 38 Step 3 assessment decision instructions

Colour code	Assessment	Assessment decision
Any pink	Pressure ulcer of category 1 or above or scarring from previous pressure ulcer	Red: secondary prevention and treatment pathway
Any orange (but no pink)	No pressure ulcer but at risk	Amber: primary prevention pathway
Only yellow and blue	Nurse to consider risk factors present and decide	Amber: primary prevention pathway *OR* green: not currently at risk pathway

Exclusion criteria

- Patients in obstetric, paediatric, day case surgery or psychiatric settings (acute or community).
- Patients deemed by the attending health-care professional to be too unwell to be approached and/or complete the study assessment schedule.

Sampling strategy

Patients were purposively sampled ensuring a similar number of hospital and community patients and representation of patients across four broad levels of risk (as defined by their mobility and ulcer status) as follows:

- no mobility restrictions
- some mobility/activity limitations
- bedfast/chairfast
- pressure ulcer category 1 or above.

Each ward/community nurse was asked to identify four patients on his or her caseload, one from each of the four broad levels of risk when possible.

Recruitment and consent

Ward-/community-based nurses identified suitable patients from their area of practice. A full verbal explanation of the study and a patient information leaflet (see *Appendix 32*) were provided by the attending clinical staff or a member of the tissue viability team and assenting patients were then invited to provide informed, written consent (see *Appendix 33*). When patients were capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent was obtained (see *Appendix 34*). In addition, to ensure that the study population was representative of the clinical population assessed in the course of usual care, when patients lacked capacity ethical approval was given for consultee agreement (see *Appendices 35* and *36*). Assessment of eligibility and informed consent was undertaken by a member of the tissue viability team. Patients who both were eligible for study participation and provided informed consent/consultee agreement were registered centrally using the CTRU automated 24-hour telephone registration system.

Data collection/assessments

Each patient recruited to the field test was assessed by only one pair of assessors.

At baseline, demographic and clinical data were recorded for each patient by the expert nurse. Baseline data included type of NHS facility (hospital/intermediate care/community nursing team), type of admission/referral (e.g. elective/acute), ward specialty (hospital patients only), date of birth, gender and ethnicity. Clinical assessment included the subscales of the Braden scale[51] and the Waterlow scale.[50]

At baseline the PURPOSE-T was completed and recorded by a member of the ward/community team and the expert nurse, blind to each other's assessment. This incorporated the detailed skin assessment and, when applicable, pressure ulcer classification.[1] The blinding was maintained through the design of a sealable research form. Both nurses were instructed to complete their assessment and seal the form prior to collection.

Finally, the expert nurse undertook a second visit and completed the PURPOSE-T and recorded clinically relevant changes to the patient's condition since the baseline assessment. The PURPOSE-T assessment was carried out blind to the baseline assessment, again maintained through the sealed research form.

The length of the test–retest interval was planned to be short enough to ensure that clinical change in the pressure ulcer was unlikely to occur but sufficiently long to ensure that the expert nurse did not recall his or her responses from the first assessment. Nurses were asked to plan their retest visit between 1 and 3 days after the baseline visit for hospital patients and between 1 and 7 days after the baseline visit for community patients, taking into account the anticipated recovery/deterioration/stability of each patient's condition and, for hospital patients, length of stay.

The expert nurses involved in data collection also kept field notes of their experience of using the PURPOSE-T in clinical practice.

Analysis considerations

Study definitions of risk

The PURPOSE-T identifies three groups of patients: those patients who are not currently at risk of developing a pressure ulcer, those patients who have no pressure ulcer but who are 'at risk' and require primary prevention and those patients with an existing pressure ulcer/scar who require secondary prevention/treatment. For the purposes of describing the study population and to assess convergent validity with other risk assessment tools, 'at risk' is defined as all patients 'who have no pressure ulcer but who are at risk' and all patients who have a 'pressure ulcer category 1 or above or scarring from previous pressure ulcers'. A patient is therefore defined as 'not at risk' if his or her outcome within the raw data was recorded as 'no pressure ulcer not currently at risk'. The cut-point used to identify patients at risk was ≤ 18 for the Braden scale[193] and ≥ 10 for the Waterlow scale.[50]

Sample size

In the study population we aimed to recruit approximately 25% of patients 'not at risk' and 75% 'at risk'. In a two-rater study, the numbers of subjects required to detect a statistically significant kappa (two-sided *p*-value ≤ 0.05) with 90% power and 75% assessed as being 'at risk', assuming a null hypothesis value for kappa, are given in *Table 39*.

To establish whether the tool gives a high degree of beyond-chance agreement, we tested against a null value of 0.6. With 90% power, 199 patients were required. To allow for withdrawal/non-compliance in paired assessments of 15%, we aimed to recruit 230 patients.

TABLE 39 Inter-rater reliability sample size estimates

Kappa to detect	Null value	Number of required patients (90% power)
0.7	0.4	114
0.7	0.5	231
0.7	0.6	793
0.8	0.4	64
0.8	0.5	103
0.8	0.6	199
0.8	0.7	536
0.9	0.4	41
0.9	0.5	58
0.9	0.6	89
0.9	0.7	159

No examples of formal sample size estimation methods for the evaluation of screening instruments were identified in the literature. Therefore, literature relating to the psychometric evaluation of rating scales was considered. The 'rule of thumb' recommendation of 5–10 patients for every item in a questionnaire was used to estimate the sample size of 115–230 patients.[194,195] The proposed sample size of 230 to assess the inter-rater reliability of the instrument, with > 95% expert nurse data compliance (based on previous research experience), was expected to provide a sufficient number of patients to assess the validity of the risk assessment instrument.

Analysis methods

Data completeness was assessed for each element of the PURPOSE-T including the percentage of missing item-level data and risk categories allocated.

We produced kappa (with 95% CI), prevalence-adjusted bias-adjusted kappa (PABAK) and the maximum value of kappa ($\kappa_{max.}$) statistics to assess the inter-rater and test–retest reliability for agreement of risk status overall (i.e. at risk/not at risk); cross-tabulations of overall risk status by rater/retest were produced. We also examined the extent of agreement for individual PURPOSE-T items using cross-tabulations by type of rater/retest. In addition, we produced kappa (with 95% CI) and weighted kappa statistics to assess the inter-rater reliability for agreement of the PURPOSE-T outcome on the 3-point scale (no risk, at risk, current pressure ulcer or pressure ulcer scarring) and produced cross-tabulations of PURPOSE-T outcome by type of rater/retest. We used guidelines to interpret kappa analysis as detailed in *Table 40*.[196,197]

Table 41 details the psychometric tests undertaken. Convergent validity assesses the degree to which constructs (or scores on a measure) expected to be related are, in fact, related. The degree to which assessment of 'at risk' and 'not at risk' is related to risk assessment status as assessed using the Braden and Waterlow risk assessment scales was determined, using cross-tabulations.

In addition, cross-tabulations of corresponding items between the PURPOSE-T and the Braden scale and/or the Waterlow scale were produced and correlation coefficients were calculated. The Spearman rank correlation coefficient was used when each of the items being compared had more than two levels, for example the Braden activity and Braden mobility subscales each have four levels and were both compared with the PURPOSE-T analysis of independent movement (which had been reduced to a 3-point scale). The phi correlation coefficient was calculated when dichotomous variables were compared, for example risk status on the Braden scale compared with risk status on the PURPOSE-T. For exploratory purposes, the following hypotheses were used as guides to the magnitude of correlations, as opposed to pass/fail benchmarks: high correlation $r > 0.7$; moderate correlation $r = 0.3$–0.7; low correlation $r < 0.3$.[198,199] Moderate to high correlations ($r \geq 0.3$) were predicted.

Known-group comparisons are used to evaluate the clinical utility of instruments or assessment tools. This method assesses the extent to which the overall assessment or items are able to discriminate between subgroups of patients known to differ in terms of clinical presentations.[200] A chi-square test for independence (used to compare the frequencies of cases found in the various categories of one variable across the different categories of another variable) was planned to determine whether or not type of hospital patient (e.g. elective vs. acute) was related to PURPOSE-T risk group as assessed by the expert nurse at baseline. However, because of the small number of elective patients this was not appropriate. No other known group was prespecified.

Field notes

The field notes were summarised and used to inform design amendments and issues of importance for implementation.

TABLE 40 Kappa interpretation guidelines

Value of kappa	Strength of agreement
< 0.20	Poor
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Good
0.81–1.00	Very good

TABLE 41 Reliability and validity psychometric tests and criteria

Test property	Definition/test	Criteria
Data quality; acceptability/ data completeness	The extent to which PURPOSE-T items are completed and used to allocate a risk category; quality of data is assessed by data completeness for each element of the PURPOSE-T and a risk category	• % item level-data missing • % of risk categories allocated • % of items missing when a risk category has been allocated
Clinical usability	Compliance with the recommended completion guidelines	• % compliance step 1 • % compliance progression to step 2 • % compliance risk allocation • qualitative review of field notes
Inter-rater reliability	Inter-rater reliability assesses the extent to which the PURPOSE-T results obtained by two or more raters agree for the same population	• The kappa statistic is a measure of true agreement and indicates the proportion of agreement beyond that expected by chance, i.e. the achieved beyond-chance agreement as a proportion of the possible beyond-chance agreement
Test–retest reliability	Test–retest reliability assesses the stability of the PURPOSE-T over a period of time in which the patient's condition is not expected to change	
Content validity	The extent to which a scale measures what it intends to measure	• Risk factor systematic review • Consensus study • Pre-test ensuring that items in the scale are representative of the construct being measured
Convergent validity (between-scale analysis – analyses against external criteria)	Evidence that PURPOSE-T constructs are correlated with other measures of the same or similar constructs, assessed on the basis of correlations between the measure and other similar measures (Braden scale and Waterlow scale)	• Correlations are expected to vary according to the degree of similarity between the constructs being measured by each instrument. Specific hypotheses are formulated and predictions tested on the basis of correlations
Known group differences	The ability of PURPOSE-T risk categories to differentiate known groups, assessed by comparing PURPOSE-T risk categories for subgroups who are expected to differ on the construct being measured (significant differences between known groups or differences of expected magnitude) (e.g. elective/acute patients)	

Results

In total, 394 patients were screened for eligibility for the study and 230 patients were registered to the study between 3 October 2012 and 25 January 2013 (*Figure 24*) from four secondary care acute hospital NHS trusts (comprising five recruiting hospitals) and four community NHS trusts, with numbers of patients registered at each centre ranging from 14 to 54 (see *Appendix 1*).

All of the 230 patients recruited were assessed in part or full using the PURPOSE-T, providing a total of 230 paired assessments undertaken by 11 expert nurses and 73 ward/community nurses. A median of three patients were assessed by each expert nurse and ward/community nurse pair. There was good representation from each of the four broad levels of risk with 53 (23.0%) patients having no mobility restrictions, 70 (30.4%) having some mobility/activity limitations, 49 (21.3%) who were bedfast/chairfast and 58 (25.2%) with an existing pressure ulcer of category 1 or above as reported at registration.

In total, 122 (53.0%) patients were recruited from community settings and 108 (47.0%) were recruited from secondary care hospital settings (*Table 42*). Of the 230 patients registered, 217 (94.3%) had retest assessments completed by the expert nurse (see *Figure 24*).

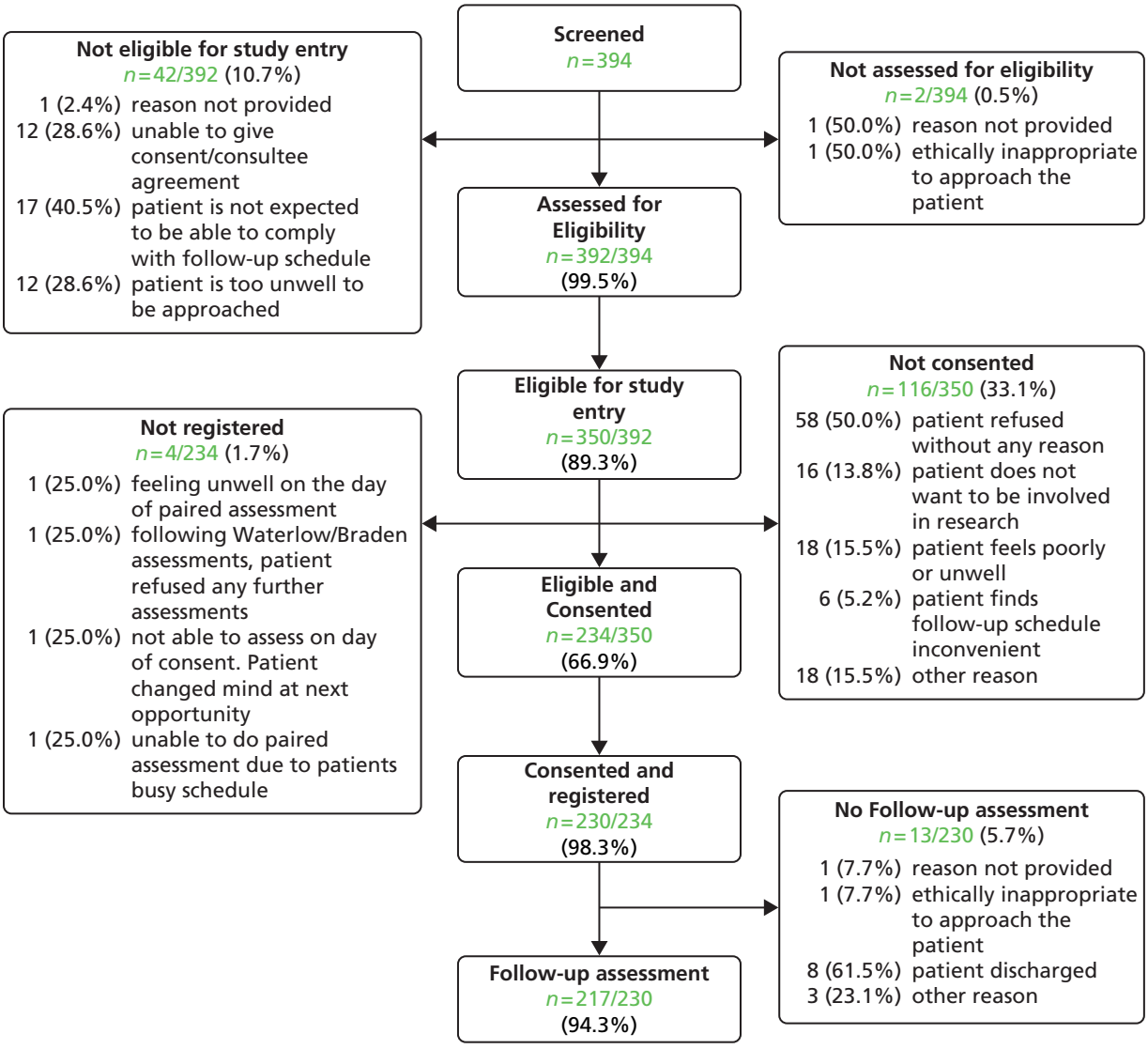

FIGURE 24 Flow of participants.

TABLE 42 Specialty or place assessed by setting

Specialty or place assessed	Acute setting ($n = 108$), *n* (%)	Community setting ($n = 122$), *n* (%)	Total ($n = 230$), *n* (%)
Patient's own home	–	47 (38.5)	47 (20.4)
Nursing home	–	3 (2.5)	3 (1.3)
Residential home	–	8 (6.6)	8 (3.5)
Rehabilitation unit	–	57 (46.7)	57 (24.8)
Other place assessed[a]	–	7 (5.7)	7 (3.0)
Medical	26 (24.1)	–	26 (11.3)
Care of the elderly	3 (2.8)	–	3 (1.3)
General/urological/gynaecological surgery	19 (17.6)	–	19 (8.3)
High-dependency unit	1 (0.9)	–	1 (0.4)
Oncology	3 (2.8)	–	3 (1.3)
Orthopaedic	19 (17.6)	–	19 (8.3)
Plastics	2 (1.9)	–	2 (0.9)
Renal	12 (11.1)	–	12 (5.2)
Spinal injury	4 (3.7)	–	4 (1.7)
Thoracic surgery	4 (3.7)	–	4 (1.7)
Vascular surgery	15 (13.9)	–	15 (6.5)

a Other places assessed were care closer to home unit ($n = 4$) and community intermediate care ($n = 3$).

The patient population comprised 99 (43.0%) men and 131 (57.0%) women. The median age was 77 years (range 19–102 years), the majority of patients were Caucasian ($n = 224$; 97.4%) and 79 (34.3%) had no activity limitation (i.e. were able to walk independently with or without a walking aid) (*Table 43*).

Based on the PURPOSE-T assessment carried out at baseline by the expert nurses, there were 60 (26.1%) patients who presented with a category 1 or above pressure ulcer. Within the community setting, 37 (30.3%) patients presented with a category 1 or above ulcer whereas, among secondary care hospital patients, 23 (21.3%) presented with a category 1 or above ulcer (see *Table 43*). There were a total of 96 pressure ulcers across the 60 patients including 21 (21.9%) category 1, 56 (58.3%) category 2, six (6.3%) category 3, six (6.3%) category 4 and seven (7.3%) unstageable ulcers (*Table 44*).

In relation to the 'at risk' status of the patient population, the Waterlow scale score identified 193 (83.9%) patients as 'at risk', the PURPOSE-T identified 183 (79.6%) patients as 'at risk' (i.e. requiring primary or secondary prevention/treatment) and the Braden scale score identified 85 (37.0%) patients as 'at risk'. The Braden scale score identified 145 patients as 'not at risk' of whom 25 (17.2%) had an existing pressure ulcer, whereas none of the patients with a pressure ulcer was assessed as 'not at risk' by either the Waterlow scale score or the PURPOSE-T (see *Table 43*).

TABLE 43 Baseline characteristics

Variable	PU at baseline[a] ($n = 60$)	No PU at baseline[a] ($n = 169$)	Missing PU status[a] ($n = 1$[b])	Total[c] ($n = 230$)
Age (years)				
Mean (SD)	73.8 (15.9)	72.1 (18.3)		72.6 (17.6)
Median (range)	76 (29–98)	78 (19–102)	78 (78–78)	77 (19–102)
Sex, *n* (%)				
Male	27 (27.3)	72 (72.7)	0 (0.0)	99 (43.0)
Female	33 (25.2)	97 (74.0)	1 (0.8)	131 (57.0)
Ethnicity, *n* (%)				
Caucasian	58 (25.9)	165 (73.7)	1 (0.4)	224 (97.4)
Other	2 (33.3)	4 (66.7)	0 (0.0)	6 (2.6)
Setting, *n* (%)				
Community	37 (30.3)	84 (68.9)	1 (0.1)	122 (53.0)
Secondary care hospital	23 (21.3)	85 (78.7)	0 (0.0)	108 (47.0)
Mobility status PURPOSE-T step 1, *n* (%)				
Walks independently with or without walking aids	10 (12.7)	69 (87.3)	0 (0.0)	79 (34.3)
Needs help of another person to walk	6 (22.2)	21 (77.8)	0 (0.0)	27 (11.7)
Spends all/majority of time in bed/chair	16 (28.1)	40 (70.2)	1 (1.8)	57 (24.8)
Remains in same position for long periods	28 (42.4)	38 (57.6)	0 (0.0)	66 (28.7)
Not completed	0 (0.0)	1 (100.0)	0 (0.0)	1 (0.4)
Braden score, *n* (%)				
At risk (≤ 18)	35 (41.2)	50 (58.8)	0 (0.0)	85 (37.0)
Not at risk (> 18)	25 (17.2)	119 (82.1)	1 (0.7)	145 (63.0)
Waterlow total score, *n* (%)				
At risk (≥ 10)	60 (31.1)	132 (68.4)	1 (0.5)	193 (83.9)
Not at risk (< 10)	0 (0.0)	37 (100.0)	0 (0.0)	37 (16.1)
PURPOSE-T risk categorisation, *n* (%)				
Secondary prevention/treatment pathway	60 (83.3)	12 (16.7)	0 (0.0)	72 (31.3)
Primary prevention pathway	0 (0.0)	111 (100)	0 (0.0)	111 (48.3)
Not currently at risk pathway	0 (0.0)	46 (97.9)	1 (2.1)	47 (20.4)

PU, pressure ulcer.

a Percentages in the PU status columns correspond to the proportion of patients within that characteristic who do (or do not) have a PU at baseline (e.g. 27.3% of the male population were observed to have a PU at baseline).

b There was one community patient for whom PU status at baseline could not be determined as no skin assessments were recorded by the tissue viability team member.

c Percentages in the total column correspond to the proportion of patients from the overall population with that characteristic (e.g. 43.0% of the overall population were male).

TABLE 44 Pressure ulcer characteristics

Variable	Expert nurse baseline assessment	Ward/community nurse assessment	Expert nurse follow-up assessment
Total population	230	230	217
Number of patients with vulnerable skin	152	156	144
Number of patients with history of PU	61	56	61
Number of patients with PU	60	62[a]	56
Total number of PUs	96	98	87
Total number of PUs per patient			
Mean (SD)	1.6 (1.1)	1.7 (1.2)[a]	1.6 (0.9)
Median (range)	1 (1–7)	1 (1–7)	1 (1–5)
Categories of reported PUs,* n *(%)			
Category 1	21 (21.9)	22 (22.4)	14 (16.1)
Category 2	56 (58.3)	41 (41.8)	50 (57.5)
Category 3	6 (6.3)	5 (5.1)	9 (10.3)
Category 4	6 (6.3)	10 (10.2)	5 (5.7)
Unstageable	7 (7.3)	7 (7.1)	9 (10.3)
Missing	0 (0.0)	13 (13.3)	0 (0.0)
Total	96	98	87

PU, pressure ulcer.

a Of the 62 patients who were identified by the ward/community nurses as having a PU, three were reported to have a PU at the screening stage but a PU was not reported in the current detailed skin assessment and therefore they have not been included in the total number of PUs reported or the grading of PUs because it is not possible to know how many PUs they might have had.

Data completeness and usability

Data completeness and usability were assessed by quantifying compliance with the completion guidelines for steps 1, 2 and 3 (*Tables 45–48*) and data completeness (*Table 49*) and analysing the qualitative reports from the expert nurses (see *Summary of expert nurse field notes*).

Progression/non-progression to step 2 was completed in line with the recommended assessment flow for 220 (95.7%) patients, including 185 (80.4%) patients who were appropriately assessed at step 2 and 35 (15.2%) patients who were allocated a decision pathway after completion of step 1 and who did not require step 2 assessments. There was one (0.4%) patient for whom no step 1 assessment was completed and there were nine (3.9%) patients who progressed to step 2 assessments when it was not required (see *Table 45*). It is of note that three of these nine patients were allocated to the 'no pressure ulcer but at risk' pathway after their step 2 assessments; one of these patients had at least one skin site assessed as vulnerable skin in step 2 but had not had this skin status selected at step 1, whereas the other two patients were assessed as 'at risk' because the expert nurses had assessed them as having a condition affecting peripheral circulation in step 2.

The expert nurses allocated a step1/step 3 decision pathway to all 230 (100%) patients, with 226 (98.3%) allocated a decision pathway as per the decision rules and four (1.7%) allocated a pathway incorrectly as at least one orange box on the PURPOSE-T had been ticked but the patients had been allocated to the 'not currently at risk' pathway (see *Table 46*).

TABLE 45 Summary of completion of the PURPOSE-T by assessment

PURPOSE-T section	Expert nurse baseline assessment	Ward/community nurse assessment	Expert nurse retest
Step 1 mobility,* n *(%)			
Completed	229 (99.6)	229 (99.6)	217 (100.0)
Not completed	1 (0.4)	1 (0.4)	0 (0.0)
Total	230 (100.0)	230 (100.0)	217 (100.0)
Progression to step 1 skin status,* n *(%)			
Mobility step 1 assessment – no mobility limitation			
Appropriate completion of step 1 skin status	78 (33.9)	84 (36.5)	63 (29.0)
Inappropriate non-completion of step 1 skin status	1 (0.4)	3 (1.3)	0 (0.0)
Mobility step 1 assessment – mobility limitation			
Appropriate completion of step 1 skin status	114 (49.6)	83 (36.1)	117 (53.9)
Inappropriate non-completion of step 1 skin status	36 (15.7)	59 (25.7)	37 (17.1)
Mobility step 1 assessment – not assessed			
Completion of step 1 skin status	0 (0.0)	1 (0.4)	0 (0.0)
Non-completion of step 1 skin status	1 (0.4)	0 (0.0)	0 (0.0)
Total	230 (100.0)	230 (100.0)	217 (100.0)
Progression to step 2 to full assessment,* n *(%)			
Potential risk identified at step 1			
Appropriate completion of step 2	185 (80.4)	185 (80.4)	179 (82.5)
Inappropriate non-completion of step 2	0 (0.0)	1 (0.4)	0 (0.0)
Not at risk at step 1			
Appropriate non-completion of step 2	35 (15.2)	32 (13.9)	35 (16.1)
Inappropriate completion of step 2	9 (3.9)	12 (5.2)	3 (1.4)
Step 1 not completed			
Step 2 completed	1 (0.4)	0 (0.0)	0 (0.0)
Total	230 (100.0)	230 (100.0)	217 (100.0)
Step 1/step 3 assessment decision allocated at step 1 or 3,* n *(%)			
Appropriate pathway	226 (98.3)	219 (95.2)	215 (99.1)
Inappropriate pathway	4 (1.7)	10 (4.3)	2 (0.9)
No pathway selected	0 (0.0)	1 (0.4)	0 (0.0)
Total	230 (100.0)	230 (100.0)	217 (100.0)

TABLE 46 Expert nurse PURPOSE-T decision pathway by the colour of boxes ticked

PURPOSE-T decision pathway	Colour of boxes ticked, *n* (%)			Total, *n* (%)
	At least one pink box ticked	No pink boxes and at least one orange box ticked	Only blue and yellow boxes ticked	
PU category 1 or above or scarring	72 (31.3)	0 (0.0)	0 (0.0)	72 (31.3)
No PU, but at risk	0 (0.0)	109 (47.4)	2 (0.9)	111 (48.3)
No PU, not currently at risk	0 (0.0)	4 (1.7)	43 (18.7)	47 (20.4)
Total	72 (31.3)	113 (49.1)	45 (19.6)	230 (100.0)

PU, pressure ulcer.

TABLE 47 Ward/community nurse PURPOSE-T decision pathway by the colour of boxes ticked

PURPOSE-T decision pathway	Colour of boxes ticked, *n* (%)			Total, *n* (%)
	At least one pink box ticked	No pink boxes and at least one orange box ticked	Only blue and yellow boxes ticked	
PU category 1 or above or scarring	63 (27.4)	0 (0.0)	0 (0.0)	63 (27.4)
No PU, but at risk	5 (2.2)	107 (46.5)	2 (0.9)	114 (49.6)
No PU, not currently at risk	0 (0.0)	5 (2.2)	47 (20.4)	52 (22.6)
Missing	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
Total	68 (29.6)	113 (49.1)	49 (21.3)	230 (100.0)

PU, pressure ulcer.

TABLE 48 Expert nurse retest PURPOSE-T decision pathway by the colour of boxes ticked

PURPOSE-T decision pathway	Colour of boxes ticked, *n* (%)			Total, *n* (%)
	At least one pink box ticked	No pink boxes and at least one orange box ticked	Only blue and yellow boxes ticked	
PU category 1 or above or scarring	68 (31.3)	0 (0.0)	0 (0.0)	68 (31.3)
No PU, but at risk	2 (0.9)	104 (47.9)	1 (0.5)	107 (49.3)
No PU, not currently at risk	0 (0.0)	0 (0.0)	42 (19.4)	42 (19.4)
Total	70 (32.3)	104 (47.9)	43 (19.8)	217 (100.0)

PU, pressure ulcer.

TABLE 49 Summary of data completeness

Construct	Number of items requiring completion	Expert nurse baseline assessment, % (*n*/*N*)	Ward/community nurse assessment, % (*n*/*N*)	Expert nurse follow-up assessment, % (*n*/*N*)	Denominator (i.e. number of items expected to have been completed)
Step 1 screening					
Mobility	1 of 4	99.6 (229/230)	99.6 (229/230)	100.0 (217/217)	All patients, as all were required to complete step 1 mobility
Skin status	1 of 4 (if required)	98.7 (78/79)	96.6 (84/87)	100.0 (63/63)	All patients for whom only the blue box was ticked in step 1 mobility
Assessment decision	1	95.3 (41/43)	85.7 (36/42)	100.0 (38/38)	All patients for whom only the blue box was ticked in both step 1 mobility and step 1 skin status
Step 2 full assessment					
Number of step 2 assessments		195	197	182	
Step 1 mobility	1 of 4	99.5 (194/195)	99.5 (196/197)	100.0 (182/182)	All patients who progressed to step 2, as all were required to complete step 1 mobility
Step 1 skin status	1 of 4 (if required)	97.7 (43/44)	96.3 (52/54)	100.0 (28/28)	All patients for whom only the blue box was ticked in step 1 mobility who progressed to step 2
Analysis of independent movement	1 of 5	99.0 (193/195)	99.0 (195/197)	98.9 (180/182)	All patients who progressed to step 2
Sensory perception and response	1 of 2	96.9 (189/195)	94.9 (187/197)	98.4 (179/182)	
Current detailed skin assessment	13	95.5 (2421/2535)	95.3 (2440/2561)	97.5 (2307/2366)	13 (number of main skin sites) times the no. of patients who progressed to step 2
Previous PU history	1 of 2	99.0 (193/195)	95.9 (189/197)	98.4 (179/182)	All patients who progressed to step 2
Previous PU details	At least 1	66.7 (40/60)	54.7 (29/53)	57.4 (35/61)	All patients reported to have a PU history in previous construct
Perfusion	At least 1	97.9 (191/195)	97.5 (192/197)	97.3 (177/182)	All patients who progressed to step 2
Nutrition	At least 1	99.0 (193/195)	99.5 (196/197)	97.8 (178/182)	
Moisture	1 of 3	99.5 (194/195)	97.0 (191/197)	96.7 (176/182)	
Diabetes	1 of 2	99.0 (193/195)	95.9 (189/197)	96.7 (176/182)	
Decision pathway allocated	1 of 3	100.0 (195/195)	99.0 (195/197)	100.0 (182/182)	
Step 1 and step 2 for those who completed step 2		96.5 (4239/4394)	95.4 (4236/4441)	97.2 (3979/4093)	Sum of all denominators for those who progressed to step 2

PU, pressure ulcer.

The follow-up expert nurse step 1 assessments were completed in line with the recommended assessment flow for 180 (82.9%) assessments (see *Table 45*). In 37 (17.1%) assessments the expert nurses completed the step 1 skin status when this was not required (i.e. patient already identified as having a mobility limitation).

Ward/community nurse assessment

The ward/community nurse form completion was similar to the expert nurse form completion. Step 1 assessments were completed in line with the recommended assessment flow for 167 (72.6%) patients. In 59 (25.7%) assessments the ward/community nurse completed the step 1 skin status assessment when this was not required (i.e. patient already identified as having a mobility limitation).

Progression/non-progression to step 2 was completed in line with the recommended assessment flow for 217 (94.3%) patients, including 185 (80.4%) patients who were appropriately assessed at step 2 and 32 (13.9%) patients who were allocated a decision pathway after completion of step 1 and who did not require step 2 assessments. There was one (0.4%) patient who should have progressed to step 2 and but did not and there were 12 (5.2%) patients who progressed to step 2 when it was not required, although it is of note that three of these patients were allocated to the 'no pressure ulcer but at risk' pathway after their step 2 assessments (see *Table 45*). The ward/community nurses allocated a step1/step 3 decision pathway to 229 (99.6%) patients, with 219 (95.2%) allocated a decision pathway as per the decision rules and 10 (4.3%) allocated a pathway incorrectly; there were five patients for whom at least one pink box had been ticked but the 'no pressure ulcer but at risk' decision pathway had been selected and there were five patients for whom at least one orange box had been ticked but the 'no pressure ulcer not currently at risk' decision pathway had been selected (see *Table 47*). It is noteworthy that the ward/community nurses also allocated the majority of patients to the 'not at risk' decision pathway when they completed only yellow and blue boxes (47/49, 95.9%; see *Table 47*).

At follow-up, progression/non-progression to step 2 was completed by the expert nurses in line with the recommended assessment flow for 214 (98.6%) patients (see *Table 45*). Only three (1.4%) patients progressed to step 2 when it was not required and they were subsequently assessed as 'not currently at risk'.

At follow-up, the expert nurses allocated a step 1/step 3 decision pathway to all 217 (100%) patients, with 215 (99.1%) patients allocated as per the decision rules and two (0.9%) patients allocated a pathway inappropriately as the expert nurses had ticked a pink box on the PURPOSE-T form but selected the 'no pressure ulcer but at risk' decision pathway (see *Table 48*).

It is noteworthy that when only yellow and blue boxes were completed the expert nurses allocated the majority of patients to the 'not at risk' decision pathway at baseline (43/45; 95.6%) and follow-up (42/43; 97.7%) (see *Tables 46* and *48*).

Inter-rater reliability

There were 230 paired assessments available for comparison; at step 1 mobility there was a total of 228 paired assessments (*Table 50*) and at the step 2 assessments there were 191 paired assessments (*Table 51*). To assess the inter-rater reliability, the maximum number of paired assessments available was used. Non-compliance with the recommended assessment flow was not taken into account to maximise the use of all available data, that is, the population used for the assessment of step 2 inter-rater reliability consisted of 191 patients for whom the step 2 assessment was completed by both raters, irrespective of whether or not they progressed to step 2 in line with the recommended assessment flow.

To compare skin assessments the 'worst' skin status recorded on the PURPOSE-T (i.e. from step 1 or step 2) was used and there were a total of 230 paired assessments (*Table 52*).

TABLE 50 Step 1 mobility: cross-tabulation of raters

	Ward/community nurse, *n* (%)				
Expert nurse	Walks independently with/without walking aids	Needs help of another person to walk	Spends all or majority of time in bed or chair	Remains in same position for long periods	Total
Walks independently with or without walking aids	72 (31.6)	1 (0.4)	5 (2.2)	0 (0.0)	78 (34.2)
Needs the help of another person to walk	4 (1.8)	14 (6.1)	8 (3.5)	1 (0.4)	27 (11.8)
Spends all or the majority of time in bed or chair	9 (3.9)	5 (2.2)	37 (16.2)	6 (2.6)	57 (25.0)
Remains in the same position for long periods	2 (0.9)	2 (0.9)	29 (12.7)	33 (14.5)	66 (28.9)
Total	87 (38.2)	22 (9.6)	79 (34.6)	40 (17.5)	228 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 51 Cross-tabulation of step 2 completion between two raters

	Ward/community nurse, *n* (%)			
Expert nurse baseline	Completed: appropriate (possible risk in step 1)	Completed: inappropriate (missing/not at risk in step 1)	Not completed	Total
Completed: appropriate (possible risk in step 1)	179 (77.8)	3 (1.3)	3 (1.3)	185 (80.4)
Completed: inappropriate (missing/not at risk in step 1)	3 (1.3)	6 (2.6)	1 (0.4)	10 (4.3)
Not completed	3 (1.3)	3 (1.3)	29 (12.6)	35 (15.2)
Total	185 (80.4)	12 (5.2)	33 (14.3)	230 (100.0)

Light green + dark green = step 2 completed by both assessors; therefore, inter-rater reliability population.
Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 52 Cross-tabulation of overall 'worst' skin status as derived from the detailed skin assessment at baseline by two raters

	Ward/community nurse, *n* (%)				
Expert nurse	Normal skin	Vulnerable skin	PU category	Missing	Total
Normal skin	54 (23.5)	11 (4.8)	1 (0.4)	2 (0.9)	68 (29.6)
Vulnerable skin	11 (4.8)	82 (35.7)	8 (3.5)	0 (0.0)	101 (43.9)
PU category	0 (0.0)	7 (3.0)	53 (23.0)	0 (0.0)	60 (26.1)
Missing	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
Total	65 (28.3)	101 (43.9)	62 (27.0)	2 (0.9)	230 (100.0)

PU, pressure ulcer.
Light green, agreement between raters that there is a problem; dark green, absolute agreement.

Decision pathway

There was agreement in the decision pathway between the expert nurse and ward/community nurse for 187 (81.7%) paired assessments (*Table 53*). The corresponding simple kappa statistic of 0.71 (95% CI 0.63 to 79) and weighted kappa of 0.76 (95% CI 0.69 to 0.83) indicate good agreement between the raters (although the 95% CI for the weighted kappa straddles the 'good' and 'very good' cut-off values).

When classified dichotomously as 'at risk'/'not at risk' there was agreement between the expert nurse and ward/community nurse for 214 (93.4%) paired assessments (*Table 54*). The corresponding simple kappa statistic of 0.81 (95% CI 0.71 to 0.90), PABAK of 0.87 and $\kappa_{max.}$ of 0.94 indicate very good agreement between raters (although the 95% CI for the simple kappa statistic straddles the 'good' and 'very good' cut-off values).

TABLE 53 Cross-tabulation of the PURPOSE-T decision pathway as recorded at baseline by two raters

	Ward/community nurse, *n* (%)			
Expert nurse	PU category 1 or above or scarring	No PU but at risk	No PU not currently at risk	Total
PU category 1 or above or scarring	54 (23.6)	18 (7.9)	0 (0.0)	72 (31.4)
No PU but at risk	9 (3.9)	91 (39.7)	10 (4.4)	110 (48.0)
No PU not currently at risk	0 (0.0)	5 (2.2)	42 (18.3)	47 (20.5)
Total	63 (27.5)	114 (49.8)	52 (22.7)	229 (100.0)

PU, pressure ulcer.
Dark green, absolute agreement.

TABLE 54 Cross-tabulation of overall risk status as assessed at baseline by two raters

	Ward/community nurse, *n* (%)		
Expert nurse	At risk	Not at risk	Total
At risk	172 (75.1)	10 (4.4)	182 (79.5)
Not at risk	5 (2.2)	42 (18.3)	47 (20.5)
Total	177 (77.3)	52 (22.7)	229 (100.0)

Dark green, absolute agreement.

Mobility

There was overall agreement between the expert nurse and the ward/community nurse for 156 (68.4%) paired assessments of step 1 mobility, with agreement that there was 'no problem' (i.e. walks independently with or without walking aids) or that there was a 'problem' for 207 (90.8%) paired assessments (see *Table 50*). At step 2 there was absolute agreement across the five possible categories for the analysis of independent movement for 113 (59.2%) paired assessments, with agreement that there was 'no problem' (i.e. moves frequently and major position changes) and that there was a 'problem' for 165 (86.4%) paired assessments (*Table 55*).

Skin status

For the three possible 'worst recorded' skin categories, there was absolute agreement for 189 (82.2%) paired assessments, with agreement that there was 'no problem' (i.e. normal skin) or that there was a 'problem' for 204 (88.7%) paired assessments (see *Table 52*).

At step 2 there was agreement between raters for no known pressure ulcer history and pressure ulcer history for 160 (83.8%) paired assessments (*Table 56*).

TABLE 55 Cross-tabulation of the analysis of independent movement at baseline by two raters

	Ward/community nurse, *n* (%)						
Expert nurse	Moves frequently and major position changes	Moves frequently and slight position changes	Moves occasionally and major position changes	Moves occasionally and slight position changes	Does not move	Not completed	Total
Moves frequently and major position changes	46 (24.1)	3 (1.6)	3 (1.6)	2 (1.0)	1 (0.5)	1 (0.5)	56 (29.3)
Moves frequently and slight position changes	2 (1.0)	5 (2.6)	7 (3.7)	9 (4.7)	1 (0.5)	0 (0.0)	24 (12.6)
Moves occasionally and major position changes	10 (5.2)	4 (2.1)	20 (10.5)	10 (5.2)	0 (0.0)	1 (0.5)	45 (23.6)
Moves occasionally and slight position changes	1 (0.5)	6 (3.1)	7 (3.7)	37 (19.4)	2 (1.0)	0 (0.0)	53 (27.7)
Does not move	0 (0.0)	1 (0.5)	1 (0.5)	4 (2.1)	5 (2.6)	0 (0.0)	11 (5.8)
Not completed	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)
Total	61 (31.9)	19 (9.9)	38 (19.9)	62 (32.5)	9 (4.7)	2 (1.0)	191 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 56 Inter-rater reliability between the expert nurses at baseline and the ward/community nurses

Expert nurse baseline	Ward/community nurse, *n* (%)			
	No known PU history	PU history	Not completed	Total
PU history				
No known PU history	116 (60.7)	9 (4.7)	4 (2.1)	129 (67.5)
PU history	15 (7.9)	44 (23.0)	1 (0.5)	60 (31.4)
Not completed	1 (0.5)	0 (0.0)	1 (0.5)	2 (1.0)
Total	132 (69.1)	53 (27.7)	6 (3.1)	191 (100.0)
	No problem	**Patient unable to feel and/or respond appropriately to discomfort from pressure**	**Not completed**	**Total**
Sensory perception				
No problem	123 (64.4)	7 (3.7)	8 (4.2)	138 (72.3)
Patient unable to feel and/or respond appropriately to discomfort from pressure	17 (8.9)	28 (14.7)	2 (1.0)	47 (24.6)
Not completed	6 (3.1)	0 (0.0)	0 (0.0)	6 (3.1)
Total	146 (76.4)	35 (18.3)	10 (5.2)	191 (100.0)
	No problem	**Problem**	**Not completed**	**Total**
Nutrition				
No problem	82 (42.9)	9 (4.7)	0 (0.0)	91 (47.6)
Problem	25 (13.1)	74 (38.7)	0 (0.0)	99 (51.8)
Not completed	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.5)
Total	107 (56.0)	84 (44.0)	0 (0.0)	191 (100.0)
	No	**Yes**	**Not completed**	**Total**
Unplanned weight loss				
No	136 (71.2)	8 (4.2)	0 (0.0)	144 (75.4)
Yes	23 (12.0)	23 (12.0)	0 (0.0)	46 (24.1)
Not completed	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.5)
Total	160 (83.8)	31 (16.2)	0 (0.0)	191 (100.0)
	No	**Yes**	**Not completed**	**Total**
Poor nutritional intake				
No	118 (61.8)	10 (5.2)	0 (0.0)	128 (67.0)
Yes	17 (8.9)	45 (23.6)	0 (0.0)	62 (32.5)
Not completed	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.5)
Total	136 (71.2)	55 (28.8)	0 (0.0)	191 (100.%)

TABLE 56 Inter-rater reliability between the expert nurses at baseline and the ward/community nurses (*continued*)

	No	Yes	Not completed	Total
Low BMI				
No	163 (85.3)	6 (3.1)	0 (0.0)	169 (88.5)
Yes	8 (4.2)	13 (6.8)	0 (0.0)	21 (11.0)
Not completed	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.5)
Total	171 (89.5)	20 (10.5)	0 (0.0)	191 (100.0)
	No	**Yes**	**Not completed**	**Total**
High BMI				
No	160 (83.8)	4 (2.1)	0 (0.0)	164 (85.9)
Yes	16 (8.4)	10 (5.2)	0 (0.0)	26 (13.6)
Not completed	1 (0.5)	0 (0.0)	0 (0.0)	1 (0.5)
Total	177 (92.7)	14 (7.3)	0 (0.0)	191 (100.0)
	Not diabetic	**Diabetic**	**Not completed**	**Total**
Diabetic status				
Not diabetic	135 (70.7)	2 (1.0)	5 (2.6)	142 (74.3)
Diabetic	1 (0.5)	45 (23.6)	1 (0.5)	47 (24.6)
Not completed	2 (1.0)	0 (0.0)	0 (0.0)	2 (1.0)
Total	138 (72.3)	47 (24.6)	6 (3.1)	191 (100.0)

PU, pressure ulcer.
Dark green, absolute agreement.

Step 2 other risk factors

Sensory perception There was agreement between raters that there was 'no problem' or that there was a 'problem' for 151 (79.1%) paired assessments, with disagreement for 24 (12.6%) paired assessments (see *Table 56*).

Nutrition There was agreement between raters for 'no problem' and 'problem' for 156 (81.7%) paired assessments. In terms of the individual nutritional assessments, there was agreement between raters for 159 (83.2%) paired assessments for unplanned weight loss, 163 (85.3%) paired assessments for poor nutritional intake, 176 (92.1%) paired assessments for low BMI and 170 (89.0%) paired assessments for high BMI (see *Table 56*).

Diabetes There was agreement between raters for diabetic status for 180 (94.2%) paired assessments, with disagreement for 3 (1.6%) paired assessments (see *Table 56*).

Perfusion There was absolute agreement across the four possible categories for 125 (65.4%) paired assessments, with agreement that there was 'no problem' or a 'problem' for 139 (72.8%) paired assessments (*Table 57*).

Moisture There was absolute agreement across the three possible categories for 145 (75.9%) paired assessments, with agreement that there was 'no problem' or a 'problem' for 155 (81.2%) paired assessments (*Table 58*).

TABLE 57 Cross-tabulation of perfusion status as assessed at baseline by two raters

	Ward/community nurse, *n* (%)					
Expert nurse	No problem	Conditions affecting central circulation	Conditions affecting peripheral circulation	Conditions affecting both central and peripheral circulation	Not completed	Total
No problem	88 (46.1)	8 (4.2)	12 (6.3)	0 (0.0)	1 (0.5)	109 (57.1)
Conditions affecting central circulation	12 (6.3)	15 (7.9)	2 (1.0)	2 (1.0)	1 (0.5)	32 (16.8)
Conditions affecting peripheral circulation	12 (6.3)	2 (1.0)	21 (11.0)	1 (0.5)	1 (0.5)	37 (19.4)
Conditions affecting both central and peripheral circulation	0 (0.0)	3 (1.6)	4 (2.1)	1 (0.5)	1 (0.5)	9 (4.7)
Not completed	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (2.1)
Total	116 (60.7)	28 (14.7)	39 (20.4)	4 (2.1)	4 (2.1)	191 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 58 Cross-tabulation of moisture status as assessed at baseline by two raters

	Ward/community nurse, *n* (%)				
Expert nurse	No problem/occasional	Frequent (two to four times a day)	Constant	Not completed	Total
No problem/occasional	133 (69.6)	14 (7.3)	2 (1.0)	3 (1.6)	152 (79.6)
Frequent (two to four times a day)	15 (7.9)	11 (5.8)	3 (1.6)	1 (0.5)	30 (15.7)
Constant	0 (0.0)	7 (3.7)	1 (0.5)	0 (0.0)	8 (4.2)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	1 (0.5)
Total	148 (77.5)	32 (16.8)	6 (3.1)	5 (2.6)	191 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

Test–retest reliability

To assess the test–retest reliability between the baseline and the retest expert nurse assessments, the maximum number of paired assessments available was used. From a possible 217 paired assessments, four were excluded as a 'change in condition' form was received, providing an analysis population of 213 paired assessments. The median number of days between the baseline and the retest expert nurse assessment was three (range 1–7). There were 213 paired assessments available for comparison of the decision pathways (*Table 59*), 212 paired assessments for comparison of step 1 mobility (*Table 60*) and 177 paired assessments for comparison of the step 2 assessments (*Table 61*). To compare skin assessments the 'worst' skin status recorded on the PURPOSE-T (i.e. from step 1 and step 2) was used and there was a total of 213 paired assessments (*Table 62*).

TABLE 59 Cross-tabulation of the PURPOSE-T decision pathway by assessment time points

	Expert nurse follow-up, *n* (%)			
Expert nurse baseline	PU category 1 or above or scarring	No PU but at risk	No PU not currently at risk	Total
PU category 1 or above or scarring	64 (30.0)	5 (2.3)	0 (0.0)	69 (32.4)
No PU but at risk	3 (1.4)	95 (44.6)	5 (2.3)	103 (48.4)
No PU not currently at risk	0 (0.0)	4 (1.9)	37 (17.4)	41 (19.2)
Total	67 (31.5)	104 (48.8)	42 (19.7)	213 (100.0)

PU, pressure ulcer.
Dark green, absolute agreement.

TABLE 60 Step 1 mobility: cross-tabulation between assessment time points

	Expert nurse follow-up, *n* (%)				
Expert nurse baseline	Walks independently with/without walking aids	Needs the help of another person to walk	Spends all or the majority of time in bed or chair	Remains in the same position for long periods	Total
Walks independently with/without walking aids	58 (27.4)	2 (0.9)	7 (3.3)	2 (0.9)	69 (32.5)
Needs help of another person to walk	2 (0.9)	15 (7.1)	7 (3.3)	1 (0.5)	25 (11.8)
Spends all or the majority of time in bed or chair	2 (0.9)	3 (1.4)	41 (19.3)	9 (4.2)	55 (25.9)
Remains in same position for long periods	0 (0.0)	1 (0.5)	11 (5.2)	51 (24.1)	63 (29.7)
Total	62 (29.2)	21 (9.9)	66 (31.1)	63 (29.7)	212[a] (100.0)

a Four patients were excluded because a 'change of condition' form had been received and one patient was excluded because the step 1 mobility assessment was not completed at both time points.
Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 61 Cross-tabulation of step 2 completion by assessment time points

Expert nurse baseline	Expert nurse follow-up, *n* (%)			
	Completed: appropriate (at risk in step 1)	Completed: inappropriate (not at risk in step 1)	Not completed: appropriate (not at risk in step 1)	Total
Completed: appropriate (at risk in step 1)	171 (80.3)	1 (0.5)	3 (1.4)	175 (82.2)
Completed: inappropriate (missing/not at risk in step 1)	3 (1.4)	2 (0.9)	0 (0.0)	5 (2.3)
Not completed: appropriate (not at risk in step 1)	1 (0.5)	0 (0.0)	32 (15.0)	33 (15.5)
Total	175 (82.2)	3 (1.4)	35 (16.4)	213[a] (100.0)

a Four patients were excluded because a 'change of condition' form had been received. Step 2 was completed correctly at both time points for these four participants.
Light green + dark green = step 2 completed at both time points, therefore test–retest reliability population.
Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 62 Cross-tabulation of overall skin status as derived from the detailed skin assessment by assessment time points

Expert nurse baseline	Expert nurse follow-up, *n* (%)			
	Normal skin	Vulnerable skin	PU category	Total
Normal skin	56 (26.3)	3 (1.4)	1 (0.5)	60 (28.2)
Vulnerable skin	8 (3.8)	84 (39.4)	3 (1.4)	95 (44.6)
PU category	0 (0.0)	6 (2.8)	51 (23.9)	57 (26.8)
Missing	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.5)
Total	64 (30.0)	94 (44.1)	55 (25.8)	213 (100.0)

PU, pressure ulcer.
Light green, agreement between raters that there is a problem; dark green, absolute agreement.

Decision pathway

There was agreement over the decision pathway between the expert nurse at baseline and the expert nurse at retest for 196 (92.0%) paired assessments (see *Table 59*). The corresponding simple kappa statistic of 0.87 (95% CI 0.81 to 0.93) and weighted kappa of 0.89 (95% CI 0.84 to 0.94) indicate very good agreement between the two assessments. When classified dichotomously as 'at risk'/'not at risk' there was agreement between the expert nurse at baseline and the expert nurse at retest for 204 (95.8%) paired assessments (*Table 63*). The corresponding simple kappa statistic of 0.87 (CI 0.78 to 0.95), PABAK of 0.92 and $\kappa_{max.}$ of 0.99 indicate very good agreement between raters (although the 95% CI for the simple kappa statistic straddles the 'good' and 'very good' cut-off values).

Mobility

There was overall agreement across the four 'worst recorded' categories for step 1 mobility for 165 (77.8%) paired assessments made by the expert nurse at baseline and at retest, with agreement that there was 'no problem' (i.e. walks independently with or without walking aids) or a 'problem' for 197 (92.9%) paired assessments (see *Table 60*). At step 2 there was absolute agreement across the five possible categories for the analysis of independent movement for 114 (64.4%) paired assessments, with agreement that there was 'no problem' (i.e. moves frequently and major position changes) or a 'problem' for 147 (83.1%) paired assessments (*Table 64*).

TABLE 63 Cross-tabulation of overall risk status by assessment time points

	Expert nurse follow-up, *n* (%)		
Expert nurse baseline	At risk	Not at risk	Total
At risk	167 (78.4)	5 (2.3)	172 (80.8)
Not at risk	4 (1.9)	37 (17.4)	41 (19.2)
Total	171 (80.3)	42 (19.7)	213 (100.0)

Dark green, absolute agreement.

TABLE 64 Cross-tabulation of the analysis of independent movement by assessment time points

	Expert nurse follow-up, *n* (%)						
Expert nurse baseline	Moves frequently and major position changes	Moves frequently and slight position changes	Moves occasionally and major position changes	Moves occasionally and slight position changes	Does not move	Not completed	Total
Moves frequently and major position changes	35 (19.8)	5 (2.8)	8 (4.5)	0 (0.0)	0 (0.0)	1 (0.6)	49 (27.7)
Moves frequently and slight position changes	7 (4.0)	6 (3.4)	2 (1.1)	7 (4.0)	0 (0.0)	0 (0.0)	22 (12.4)
Moves occasionally and major position changes	6 (3.4)	6 (3.4)	31 (17.5)	2 (1.1)	0 (0.0)	0 (0.0)	45 (25.4)
Moves occasionally and slight position changes	2 (1.1)	8 (4.5)	4 (2.3)	33 (18.6)	2 (1.1)	0 (0.0)	49 (27.7)
Does not move	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)	9 (5.1)	0 (0.0)	11 (6.2)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	50 (28.2)	25 (14.1)	45 (25.4)	44 (24.9)	11 (6.2)	2 (1.1)	177 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

Skin status

For the three possible 'worst recorded' skin categories, there was absolute agreement for 191 (89.7%) paired assessments, with agreement that there was 'no problem' (i.e. normal skin) or a 'problem' for 200 (93.9%) paired assessments (see *Table 62*). At step 2 there was agreement between ratings of 'no known pressure ulcer history' and 'pressure ulcer history' for 165 (93.2%) paired assessments (*Table 65*).

TABLE 65 Test–retest reliability between the expert nurse at baseline and the expert nurse at retest

	Expert nurse follow-up, *n* (%)			
Expert nurse baseline	No known PU history	PU history	Not completed	Total
PU history				
No known PU history	110 (62.1)	4 (2.3)	3 (1.7)	117 (66.1)
PU history	3 (1.7)	55 (31.1)	0 (0.0)	58 (32.8)
Not completed	2 (1.1)	0 (0.0)	0 (0.0)	2 (1.1)
Total	115 (65.0)	59 (33.3)	3 (1.7)	177 (100.0)
	No problem	**Patient unable to feel and/or respond appropriately to discomfort from pressure**	**Not completed**	**Total**
Sensory perception				
No problem	118 (66.7)	6 (3.4)	2 (1.1)	126 (71.2)
Patient unable to feel and/or respond appropriately to discomfort from pressure	10 (5.6)	36 (20.3)	0 (0.0)	46 (26.0)
Not completed	3 (1.7)	1 (0.6)	1 (0.6)	5 (2.8)
Total	131 (74.0)	43 (24.3)	3 (1.7)	177 (100.0)
	No problem	**Problem**	**Not completed**	**Total**
Nutrition				
No problem	77 (43.5)	7 (4.0)	3 (1.7)	87 (49.2)
Problem	12 (6.8)	77 (43.5)	0 (0.0)	89 (50.3)
Not completed	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	89 (50.3)	84 (47.5)	4 (2.3)	177 (100.0)
	No	**Yes**	**Not completed**	**Total**
Unplanned weight loss				
No	127 (71.8)	4 (2.3)	3 (1.7)	134 (75.7)
Yes	10 (5.6)	32 (18.1)	0 (0.0)	42 (23.7)
Not completed	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	137 (77.4)	36 (20.3)	4 (2.3)	177 (100.0)

TABLE 65 Test–retest reliability between the expert nurse at baseline and the expert nurse at retest (*continued*)

	No	Yes	Not completed	Total
Poor nutritional intake				
No	114 (64.4)	6 (3.4)	3 (1.7)	123 (69.5)
Yes	8 (4.5)	45 (25.4)	0 (0.0)	53 (29.9)
Not completed	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	122 (68.9)	51 (28.8)	4 (2.3)	177 (100.0)
	No	**Yes**	**Not completed**	**Total**
Low BMI				
No	152 (85.9)	0 (0.0)	3 (1.7)	155 (87.6)
Yes	3 (1.7)	18 (10.2)	0 (0.0)	21 (11.9)
Not completed	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	155 (87.6)	18 (10.2)	4 (2.3)	177 (100.0)
	No	**Yes**	**Not completed**	**Total**
High BMI				
No	143 (80.8)	4 (2.3)	3 (1.7)	150 (84.7)
Yes	4 (2.3)	22 (12.4)	0 (0.0)	26 (14.7)
Not completed	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	147 (83.1)	26 (14.7)	4 (2.3)	177 (100.0)
	Not diabetic	**Diabetic**	**Missing**	**Total**
Diabetic status				
Not diabetic	123 (69.5)	0 (0.0)	6 (3.4)	129 (72.9)
Diabetic	3 (1.7)	43 (24.3)	0 (0.0)	46 (26.0)
Not completed	2 (1.1)	0 (0.0)	0 (0.0)	2 (1.1)
Total	128 (72.3)	43 (24.3)	6 (3.4)	177 (100.0)

PU, pressure ulcer.
Dark green, absolute agreement.

Other step 2 risk factors

Sensory perception There was agreement between ratings that there was 'no problem' or a 'problem' for 154 (87.0%) paired assessments (see *Table 65*).

Nutrition There was agreement between ratings that there was 'no problem' or a 'problem' for 154 (87.0%) paired assessments. In terms of the individual nutritional assessments, there was agreement between ratings for 159 (89.9%) paired assessments for unplanned weight loss, 159 (89.8%) paired assessments for poor nutritional intake, 170 (96.0%) paired assessments for low BMI and 165 (93.2%) paired assessments for high BMI (see *Table 65*).

Diabetes There was agreement over diabetic status for 166 (93.8%) paired assessments (see *Table 65*).

Perfusion There was absolute agreement across the four possible categories of perfusion for 138 (78.0%) paired assessments, with agreement that there was 'no problem' or 'problem' for 154 (87.0%) paired assessments (*Table 66*).

Moisture There was absolute agreement across the three possible categories of moisture for 155 (87.6%) paired assessments, with agreement that there was 'no problem' or a 'problem' for 159 (89.8%) paired assessments (*Table 67*).

TABLE 66 Cross-tabulation of perfusion status by assessment time points

	Expert nurse follow-up, *n* (%)					
Expert nurse baseline	No problem	Conditions affecting central circulation	Conditions affecting peripheral circulation	Conditions affecting both central and peripheral circulation	Not completed	Total
No problem	87 (49.2)	0 (0.0)	8 (4.5)	0 (0.0)	4 (2.3)	99 (55.9)
Conditions affecting central circulation	6 (3.4)	19 (10.7)	3 (1.7)	4 (2.3)	0 (0.0)	32 (18.1)
Conditions affecting peripheral circulation	1 (0.6)	3 (1.7)	28 (15.8)	2 (1.1)	0 (0.0)	34 (19.2)
Conditions affecting both central and peripheral circulation	0 (0.0)	1 (0.6)	3 (1.7)	4 (2.3)	0 (0.0)	8 (4.5)
Not completed	3 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	4 (2.3)
Total	97 (54.8)	23 (13.0)	42 (23.7)	10 (5.6)	5 (2.8)	177 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

TABLE 67 Cross-tabulation of moisture status by assessment time points

	Expert nurse follow-up, *n* (%)				
Expert nurse baseline	No problem/occasional	Frequent (two to four times a day)	Constant	Not completed	Total
No problem/occasional	126 (71.2)	7 (4.0)	0 (0.0)	5 (2.8)	138 (78.0)
Frequent (two to four times a day)	5 (2.8)	24 (13.6)	1 (0.6)	0 (0.0)	30 (16.9)
Constant	0 (0.0)	3 (1.7)	5 (2.8)	0 (0.0)	8 (4.5)
Not completed	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)
Total	131 (74.0)	34 (19.2)	6 (3.4)	6 (3.4)	177 (100.0)

Light green, agreement between raters that there is a problem; dark green, absolute agreement.

Convergent validity

PURPOSE-T step 1

Mobility The mobility assessment at step 1 of the PURPOSE-T was compared with the Braden mobility and activity subscales using dichotomous scales (i.e. 'problem' or 'no problem'). The step 1 mobility assessment on the PURPOSE-T was found to have a moderate association with both the Braden mobility subscale and the Braden activity subscale, with phi correlation coefficients of 0.60 and 0.66 respectively (*Table 68*).

Skin The 'worst' overall PURPOSE-T skin status was compared with the 'worst' Waterlow skin status. There was a high association observed between the PURPOSE-T skin status and the Waterlow skin status, with a Spearman rank correlation coefficient of 0.83 (*Table 69*).

PURPOSE-T step 2

Analysis of independent movement The PURPOSE-T analysis of independent movement was compared with the Braden mobility and activity subscales. The analysis of independent movement was observed to be moderately associated with both the Braden mobility subscale and the Braden activity subscale, with corresponding Spearman rank correlation coefficients of 0.62 and 0.55 respectively (see *Table 69*).

Sensory perception and response The sensory perception and response assessment on the PURPOSE-T was compared with the Braden sensory perception score. A high association between the two sensory perception assessments was observed, with a corresponding phi correlation coefficient of 0.74 (see *Table 68*).

Nutrition A moderate association was observed between 'problem'/'no problem' on the PURPOSE-T nutrition construct and the Braden nutrition subscale (dichotomised to 'excellent or adequate'/'probably inadequate or very poor'), with a phi correlation coefficient of 0.58, and between 'problem'/'no problem' on the PURPOSE-T nutrition construct and the Waterlow malnutrition screening tool (part c: eating poorly or has a lack of appetite), with a phi correlation coefficient of 0.60 (see *Table 68*).

A high association was observed between 'poor nutritional intake' ('yes'/'no') on the PURPOSE-T and the Braden nutrition subscale (dichotomised to 'excellent or adequate'/'probably inadequate or very poor'), with a phi correlation coefficient of 0.82. A high association was also observed between 'poor nutritional intake' ('yes'/'no') on the PURPOSE-T and the Waterlow malnutrition screening tool (part c: eating poorly or has a lack of appetite), with a phi correlation coefficient of 0.79; between 'low BMI' ('yes'/'no') on the

TABLE 68 Cross-tabulation of PURPOSE-T, Braden and Waterlow construct measures

	Braden mobility, *n* (%)			
PURPOSE-T step 1 mobility	No limitation	Slightly/very limited/completely immobile	Total	Correlation coefficient
No problem	69 (30.1)	10 (4.4)	79 (34.5)	Phi 0.60 – moderate
Problem	37 (16.2)	113 (49.3)	150 (65.5)	
Total	106 (46.3)	123 (53.7)	229 (100.0)	
	Braden activity, *n* (%)			
PURPOSE-T step 1 mobility	Walks frequently	Walks occasionally, chairfast or bedfast	Total	Correlation coefficient
No problem	56 (24.5)	23 (10.0)	79 (34.5)	Phi 0.66 – moderate
Problem	11 (4.8)	139 (60.7)	150 (65.5)	
Total	67 (29.3)	162 (70.7)	229 (100.0)	
	Braden sensory perception, *n* (%)			
PURPOSE-T sensory response and perception	No impairment	Slightly, very or completely limited	Total	Correlation coefficient
No problem	134 (70.9)	7 (3.7)	141 (74.6)	Phi 0.74 – high
Patient unable to feel and/or respond appropriately to discomfort from pressure	11 (5.8)	37 (19.6)	48 (25.4)	
Total	145 (76.7)	44 (23.3)	189 (100.0)	
	Braden nutrition, *n* (%)			
PURPOSE-T nutrition	Excellent or adequate	Probably inadequate or very poor	Total	Correlation coefficient
No problem	93 (48.2)	1 (0.5)	94 (48.7)	Phi 0.58 – moderate
Problem	47 (24.4)	52 (26.9)	99 (51.3)	
Total	140 (72.5)	53 (27.5)	193 (100.0)	
	Waterlow malnutrition screening tool: patient eating poorly or lack of appetite, *n* (%)			
PURPOSE-T nutrition	Yes	No	Total	Correlation coefficient
Problem	64 (33.7)	35 (18.4)	99 (52.1)	Phi 0.60 – moderate
No problem	6 (3.2)	85 (44.7)	91 (47.9)	
Total	70 (36.8)	120 (63.2)	190 (100.0)	
	Braden nutrition, *n* (%)			
PURPOSE-T nutrition: poor nutritional intake	Probably inadequate or very poor	Excellent or adequate	Total	Correlation coefficient
Yes	50 (25.9)	12 (6.2)	62 (32.1)	Phi 0.82 – high
No	3 (1.6)	128 (66.3)	131 (67.9)	
Total	53 (27.5)	140 (72.5)	193 (100.0)	

TABLE 68 Cross-tabulation of PURPOSE-T, Braden and Waterlow construct measures (*continued*)

PURPOSE-T nutrition: poor nutritional intake	Waterlow malnutrition screening tool: patient eating poorly or lack of appetite, *n* (%)			Correlation coefficient
	Yes	No	Total	
Yes	57 (30.0)	5 (2.6)	62 (32.6)	Phi 0.79 – high
No	13 (6.8)	115 (60.5)	128 (67.4)	
Total	70 (36.8)	120 (63.2)	190 (100.0)	
PURPOSE-T nutrition: low BMI	**Waterlow build or weight for height, *n* (%)**			**Correlation coefficient**
	BMI < 20 kg/m²	**BMI ≥ 20 kg/m²**	**Total**	
Yes	21 (11.0)	0 (0.0)	21 (11.0%)	Phi 0.72 – high
No	16 (8.4)	154 (80.6)	170 (89.0%)	
Total	37 (19.4)	154 (80.6)	191 (100.0%)	
PURPOSE-T nutrition: high BMI	**Waterlow build or weight for height, *n* (%)**			**Correlation coefficient**
	BMI ≥ 30 kg/m²	**BMI < 30 kg/m²**	**Total**	
Yes	22 (11.5)	4 (2.1)	26 (13.6)	Phi 0.74 – high
No	9 (4.7)	156 (81.7)	165 (86.4)	
Total	31 (16.2)	160 (83.8)	191 (100.0)	

Dark green, absolute agreement.

TABLE 69 Cross-tabulation of PURPOSE-T, Braden and Waterlow construct measures

PURPOSE-T step 2 analysis of independent movement	Braden mobility, *n* (%)				Correlation coefficient
	Completely immobile	Very or slightly limited	No limitation	Total	
Does not move	7 (3.6)	4 (2.1)	0 (0.0)	11 (5.7)	Spearman rank 0.62 – moderate
Moves occasionally and slight or major position changes or moves frequently with slight position changes	1 (0.5)	96 (49.7)	26 (13.5)	123 (63.7)	
Moves frequently and major position changes	0 (0.0)	12 (6.2)	47 (24.4)	59 (30.6)	
Total	8 (4.1)	112 (58.0)	73 (37.8)	193 (100.0)	
PURPOSE-T step 2 analysis of independent movement	**Braden activity, *n* (%)**				**Correlation coefficient**
	Bedfast	Chairfast or walks occasionally	Walks frequently	Total	
Does not move	6 (3.1)	5 (2.6)	0 (0.0)	11 (5.7)	Spearman rank 0.55 – moderate
Moves occasionally and slight or major position changes or moves frequently with slight position changes	15 (7.8)	102 (52.8)	6 (3.1)	123 (63.7)	
Moves frequently and major position changes	0 (0.0)	31 (16.1)	28 (14.5)	59 (30.6)	
Total	21 (10.9)	138 (71.5)	34 (17.6)	193 (100.0)	
PURPOSE-T skin status	**Waterlow skin status, *n* (%)**				**Correlation coefficient**
	Healthy	Tissue paper, dry, oedematous, clammy	Discoloured grade 1 or broken spots grades 2–4	Total	
Normal skin	47 (20.6)	18 (7.9)	0 (0.0)	65 (28.5)	Spearman rank 0.83 – high
Vulnerable skin	11 (4.8)	79 (34.6)	13 (5.7)	103 (45.2)	
PU category	1 (0.4)	0 (0.0)	59 (25.9)	60 (26.3)	
Total	59 (25.9)	97 (42.5)	72 (31.6)	228 (100.0)	
PURPOSE-T moisture	**Braden moisture, *n* (%)**				**Correlation coefficient**
	Rarely or occasionally moist	Very moist	Constantly moist	Total	
No problem/occasional	154 (79.4)	2 (1.0)	0 (0.0)	156 (80.4)	Spearman rank 0.67 – moderate
Frequent (two to four times a day)	18 (9.3)	12 (6.2)	0 (0.0)	30 (15.5)	
Constant	0 (0.0)	4 (2.1)	4 (2.1)	8 (4.1)	
Total	172 (88.7)	18 (9.3)	4 (2.1)	194 (100.0)	

PU, pressure ulcer.
Dark green, absolute agreement.

PURPOSE-T and the Waterlow build/weight for height construct, with a phi correlation coefficient of 0.72; and between 'high BMI' ('yes'/'no') on the PURPOSE-T and the Waterlow build/weight for height construct, with a phi correlation coefficient of 0.74.

Moisture The PURPOSE-T moisture assessment was compared with the Braden moisture assessment. A moderate association was observed between the moisture assessment on the PURPOSE-T and the Braden moisture assessment, with a Spearman rank correlation coefficient of 0.67 (see *Table 69*).

Assessment decision

Overall A moderate association was observed between the overall risk status on the PURPOSE-T and the Waterlow scale score for all patients, as assessed by the expert nurse at baseline, with a phi correlation coefficient of 0.63 (*Table 70*).

Pressure ulcer-free patients There was a moderate association observed between the overall risk status on the PURPOSE-T and the Braden scale score for pressure ulcer-free patients, as assessed by the expert nurse at baseline, with a phi correlation coefficient of 0.40.

Summary of expert nurse field notes

The field notes (incorporating the views of expert nurses using the tool as well as the views of some ward/community nurses who provided feedback to the expert nurses, although exact numbers are unknown) described positive and problem aspects of using the PURPOSE-T in practice, as detailed in *Table 71*.

In addition, other problematic aspects of assessment that are common to all risk assessment instruments were also reported including:

- lack of knowledge of pressure ulcer classification
- difficulty assessing mobility when the patient is unable to communicate and when the patient has been seen for only a short period before assessment
- difficulty assessing sensory perception
- difficulty assessing medical history in the community setting
- difficulty assessing poor nutritional intake
- difficulty assessing BMI in the community setting.

TABLE 70 Cross-tabulation of overall risk status at baseline between the PURPOSE-T and the Waterlow scale

	Waterlow risk status, *n* (%)			
PURPOSE-T risk status	At risk (≥ 10)	Not at risk (< 10)	Total	Correlation coefficient
At risk	175 (76.1)	8 (3.5)	183 (79.6)	Phi 0.63 – moderate
Not at risk	18 (7.8)	29 (12.6)	47 (20.4)	
Total	193 (83.9)	37 (16.1)	230 (100.0)	
	Braden risk status, *n* (%)[a]			
PURPOSE-T risk status	At risk (≥ 10)	Not at risk (< 10)	Total	Correlation coefficient
At risk	50 (29.6)	73 (43.2)	123 (72.8)	Phi 0.40 – moderate
Not at risk	0 (0.0)	46 (27.2)	46 (27.2)	
Total	50 (29.6)	119 (70.4)	169 (100.0)	

a Only patients reported as being pressure ulcer free at baseline were included.
Dark green, absolute agreement.

TABLE 71 Summary of the expert nurse field notes

Characteristic	Positive aspects of using the PURPOSE-T	Problem aspects of using the PURPOSE-T
Layout	• Easy to use and self-explanatory • Quick to use • Easier to use with familiarity • All on one page	• Tool looked 'busy' or 'complicated' • Font size small • Space for skin assessment too small
Format	• The RAG rating approach for assessment decision and use of colour made distinctive • Like the fact it did not use a score like other risk assessment scales	• Form does not flow • Unclear whether or not to progress to step 2 • Concern that exiting at step 1 would miss assessment of important risk factors • Nurses wanted to complete full skin assessment at step 1
Content	• Thorough and included important risk factors • Positive about the detailed skin assessment and suggested that this encouraged a more careful skin assessment • Inclusion of pressure ulcer scar as a risk factor	• Reliability of assessment of skin vulnerability • Reliability of assessment of scarring • Difficulty establishing history of previous pressure ulcers: difficult and time-consuming; when information available was of poor quality (e.g. severity not clear) • Duration of weight loss not specified • Assessment of circulation items in patients with respiratory problems • Analysis of movement difficult to categorise
Usability	• Will be easy for nurses to remember and report red boxes at handover • Step 1 screening is efficient in allowing the quick identification of those who do not require a full assessment • Not having to visually inspect pressure areas when a patient was not at risk was appreciated	• Local production difficult if no colour printers available

Final amendments to the PURPOSE-T

Field test amendments

The field test results informed revisions and the production of the final PURPOSE-T and associated user manual. Revisions included:

- increasing the font size and spacing of the skin assessment section by moving the 'vulnerable skin' descriptors to the classification box
- further clarification of examples of skin vulnerability relating to skin redness
- amendment of the flow of step 2 by moving the skin assessment section
- simplification of the 'previous pressure ulcer history' item, encouraging nurses to record the number of previous pressure ulcers and to give a detailed account of the pressure ulcer that left a scar or the worst category pressure ulcer rather than all previous pressure ulcers.

Changes to the user manual were undertaken to reflect the changes made to the PURPOSE-T, detailed above. In addition, further guidance was included in the manual relating to:

- parameters of weight loss and time periods
- nutritional intake and support
- assessment of BMI.

Consideration of new evidence from the pain cohort study

In the original programme grant timelines the pain cohort study should have concluded before the start of the risk assessment work package. In practice this did not happen because of the late start of the pain cohort study and the extended recruitment period required to deliver the study. Instead, there were some preliminary expert group discussions about pain in the expert group meetings and we adjusted the original consensus study to enable later consideration of the pain cohort study results.

As before, the consensus process involved a face-to-face meeting with PURSUN UK members. PURSUN UK members recognised pain as an important sign, noting that the results of the pain study reflected people's personal experiences of pain (e.g. feeling discomfort before redness appears on the skin). They supported the inclusion of pain in the PURPOSE-T.

The expert group element was conducted by questionnaire alone. Expert group members privately completed an initial questionnaire that incorporated the results of the pain cohort study, the views of PURSUN UK and follow-up notes. They were asked to consider this evidence and rate their level of support for the inclusion of pain at the screening and full assessment stages of the PURPOSE-T (on a 9-point Likert scale) and to make comments regarding this. The results of the initial questionnaire, including the median group response, disagreement index and anonymised expert group comments (as well as the evidence included in the initial pain questionnaire), were incorporated into a follow-up questionnaire, allowing expert group members to consider the views of others before privately re-rating their level of support for the inclusion of pain in the PURPOSE-T. The results of this follow-up pain questionnaire determined whether or not pain was included in the PURPOSE-T, following the same criteria used in the original consensus study (see *Phase 2: consensus study, Data analysis*).

The results indicated that, although there was uncertainty regarding the inclusion of pain at the screening stage of the assessment, there was support for its inclusion at the full assessment stage and it was subsequently incorporated as an extension to the pressure ulcer and skin assessment section of the PURPOSE-T.

Discussion

A new Risk Assessment Framework – PURPOSE-T [incorporating a risk factor Minimum Data Set; see http://medhealth.leeds.ac.uk/accesspurposet (accessed July 2015)] – was developed to enhance pressure ulcer risk assessment practice. We were unable to use gold standard methods for the development of a risk stratification tool using multivariable modelling because of the lack of standard recording of key risk factors and appropriate data sets to identify items for a risk tool, with subsequent model testing on a 'new' prospective target population.[122] Rather, we undertook a systematic review incorporating a narrative synthesis of pressure ulcer risk factors to provide the foundation for a consensus study to agree a risk factor Minimum Data Set for inclusion in a new Risk Assessment Framework. This will facilitate the routine and standardised recording of risk factors in clinical practice and can be used for modelling and ongoing development. The PURPOSE-T underwent rigorous pre-testing and field testing with expert and ward/community nurses and has good face, content and construct validity and good and very good inter-rater and test–retest reliability respectively.

The systematic review allowed the risk factors that are independently associated with pressure ulcer development to be identified,[46] providing a clearer notion of the critical pressure ulcer risk factors. However, there are remaining gaps in the literature for some potentially important risk factors, which require further research. In addition, pressure ulcer risk factors were inconsistently represented in the modelling of the primary studies of the systematic review and this limits both the interpretation and the overall conclusions. Other limitations of the literature include poor reporting, heterogeneity of patient populations, use of different outcomes, lack of differentiation between ulcer sites and the observation of mainly superficial pressure ulcers. Although the evidence of the systematic review provides a good insight

into the risk factors associated with pressure ulcer development at a population level, it does not fully explain the underlying pathology of pressure ulcer development, and wider scientific evidence, and its relevance to clinical practice, must also be considered. Finally, it is acknowledged that, in the absence of a standard method for appraising the quality of risk factor research, we developed study-specific criteria and categorised studies as high, medium, low and very low quality, which has a number of inherent limitations.

The consensus study allowed the evidence of the systematic review to be carefully reviewed by an expert group, taking into account the wider scientific evidence, its relevance to clinical practice and the views of PURSUN UK. The consensus methods were particularly useful in allowing the expert group to agree the key risk factors to summarise patient risk (i.e. those that were considered to increase the probability of pressure ulcer development). Although the methods were also useful for identifying the key principles of the assessment items, they were inappropriate for considering the specific wording of items. Of note is the agreement that the risk factors and assessment items should be the same for the Minimum Data Set and the Risk Assessment Framework (i.e. no additional risk factor information was considered necessary for assessment in clinical practice). It was acknowledged that risk factors excluded from the Minimum Data Set and Risk Assessment Framework may still have a role in the pressure ulcer causal pathway through their relationship with the agreed risk factors and may be important at an individual patient level (e.g. the use of sedative medication may limit a patient's mobility/activity and this would be addressed in the related items of the Risk Assessment Framework). Whereas some of the agreed risk factors emerged as primary risk factors in the systematic review [immobility, existing pressure ulcer, general skin status, perfusion (including diabetes)], others, although still important, emerged less consistently (moisture, nutrition, sensory perception) and two risk factors (previous pressure ulcer and pain) did not emerge in the systematic review. Previous pressure ulcer was included on the basis of service user opinion and theoretical bioengineering evidence (particularly relating to scarring) rather than on the basis of the epidemiological evidence. Pain was included following the availability of the results of the pain cohort study. Although all acknowledged that the epidemiological evidence was derived from a single study, its inclusion was influenced by the strength of the multivariable modelling, general pathophysiological principles and service user opinion. Conversely, albumin, which emerged more consistently in the systematic review and was initially agreed by the expert group for inclusion (in the full assessment stage of the Minimum Data Set and Risk Assessment Framework), was subsequently excluded because of concerns raised by PURSUN UK. In these examples, when the group diverged from the scientific evidence, the reasons were in keeping with some of those previously reported including clinical experience and patient preference.[201]

The integration of the PURSUN UK perspective throughout the study proved invaluable and to our knowledge is the first study to use such an approach. Whereas others using consensus methods have incorporated patient/carer representation in their expert groups,[202,203] we decided to use an alternative approach when developing the study methodology. This was because of a concern that the complexity of the epidemiological and wider scientific evidence, as well as the complex nature of facilitating a mixed group of patients and professionals, could have impeded the patients' and carers' input into the process. Difficulties in involving patients and carers in the development of technical and clinical guidelines have been raised previously[204] and for this study there seemed to be more value in devoting whole meetings to patient/carer insights, with particular emphasis on the acceptability of elements of assessment. This allowed us to consider the views of a larger number of service users. We were conscious of the need to integrate PURSUN UK members' perspectives into the consensus process and this was carried out by feedback at the expert group meetings or inclusion of their comments into questionnaires, so that the group could consider the patient/carer perspective alongside other evidence.

Although the consensus study involved an expert group with considerable experience, a limitation of consensus methodology relates to reliability and whether or not the results of this study are representative of the views of other experts in the field. Raine and colleagues[182] proposed a new approach to developing clinical guidelines that includes checking the representativeness of the group's ratings with a large similarly composed group. As it is our intention to continually update the Risk Assessment Framework, further work is currently being planned to validate the Minimum Data Set and Risk Assessment Framework through consultation with a

larger group. This will also allow new evidence to be brought forward and integrated into the work. Another difficulty associated with consensus methods relates to validity and assessing whether or not the judgements made by the group are 'good'.[181] Although we developed a consensus method (incorporating group expertise, relevant evidence and group facilitation) to facilitate 'good judgements' regarding the inclusion of risk factors and assessment items in the risk factor Minimum Data Set and Risk Assessment Framework, we were unable to assess this at the time of conducting the study. This should be assessed in future modelling work and the ongoing development of PURPOSE-T to establish whether the judgements of the consensus study are correct.

Building on the work of the consensus study we were able to develop a theoretical causal pathway for pressure ulcer development and a new conceptual framework, to bring together the epidemiological, physiological and biomechanical evidence, enhancing our understanding of the role of individual risk factors in pressure ulcer development. However, there is remaining uncertainty about how varying combinations of risk factors and their parameters (e.g. varying levels of mobility, nutrition, moisture) impact on pressure ulcer outcome as well as aetiological mechanisms of importance (e.g. uncertainty about the specific mechanisms of importance relating to perfusion). The importance of individual risk factors may also vary in relation to body site (e.g. a patient with peripheral vascular disease may have reduced tolerance to pressure to their heels but not to their trunk areas). The development of the conceptual framework through the combination of bioengineering and epidemiological expertise and evidence also highlights that currently the methods that we have to assess the direct and indirect causal factors involved in pressure ulcer development, including the mechanical boundary conditions and factors affecting tissue tolerance (geometry, mechanical properties of tissue, transport and thermal properties and physiology and repair), are very crude clinical assessments. The work provides a foundation for a programme of bioengineering and translational research to develop improved assessment techniques with greater precision for clinical use.

The pre-test allowed us to identify areas of confusion and improve the usability and acceptability of the Risk Assessment Framework for clinical nurses. It could be argued that undertaking a pre-test using vignette case studies is no substitute for assessing the Risk Assessment Framework in clinical practice. However, assessing and improving the acceptability of the Risk Assessment Framework with clinical nurses was considered a necessary and logical step to ensure face and content validity before evaluation in clinical practice with real patients. The vignettes were developed to be realistic, with input from the clinical members of the project team and members of PURSUN UK. The focus groups and think out loud interviews were held in a pleasant environment and were carefully planned to encourage disclosure among participants, which would not have been possible in a busy clinical area. In addition, topic guides were used by trained facilitators, group numbers were conducive to facilitation, nurses from different trusts were grouped according to job role and participants were fully briefed and had opportunities to ask questions before the actual interviews/focus groups.

The pre-test facilitated changes to the Risk Assessment Framework relating to three main areas, including the flow and format of the tool, decision support and the wording of specific items. This led to the development of a preliminary Risk Assessment Framework – PURPOSE-T – in readiness for clinical evaluation.

The field test of the PURPOSE-T involved 230 patients who were assessed by both expert and ward/community nurses. Apart from previous pressure ulcer history, the level of data completion for expert and ward/community nurse assessments for each construct on the PURPOSE-T was high at > 90%. The inter-rater and test–retest agreement was 'very good' for the assessment decision overall as determined by kappa. The percentage agreement for the assessment of 'problem/no problem' for the eight risk factors (mobility, skin, previous pressure ulcer, sensory perception, perfusion, nutrition, moisture and diabetes) ranged from 79.1% to 94.2% for inter-rater reliability and from 87.0% to 93.9% for test–retest reliability. Moderate to high associations were demonstrated for convergent validity, assessed by comparison with the same or similar constructs on other risk assessment scales (Braden and Waterlow). A known group comparison was not possible because of the small number of patients recruited from elective wards.

In addition, field notes recorded by the expert nurses highlighted positive and problem aspects of using the tool in the clinical environment. Negative aspects included difficulties in assessing some of the PURPOSE-T items and concerns about reliability, but these were not evidenced in the formal evaluation of inter-rater and test–retest reliability.

It is of note that both expert and ward/community nurses allocated the majority of patients (> 95%) to the 'not at risk' category, with only 'yellow' and 'blue' boxes completed (see *Tables 45–47*). This means that these patients did not have skin, sensory perception, perfusion or major mobility problems but were characterised by minor mobility limitations with or without nutritional deficits, moisture problems or a history of previous pressure ulcers (with no scar). This is interesting because these factors do not emerge consistently in multivariable modelling (see *Phase 1: Systematic review of patient risk factors for pressure ulcer development*, *Emerging risk factor domains/subdomains*), were still judged to be important in the consensus development process, but colour coded as 'yellow' (i.e. requiring clinical judgement). It may be that in practice they are judged to be not important in the absence of the other key risk factors. The next stage of the development process will involve the dissemination of the PURPOSE-T into routine NHS care and this will facilitate large-scale multivariable modelling and predictive validity testing, allowing further refinement of the tool.

The main differences between the PURPOSE-T and other widely used risk assessment tools are as follows:

- a risk factor Minimum Data Set is incorporated to facilitate multivariable modelling
- involves a screening stage for all patients and a full assessment stage for those at potential/actual risk or with an existing pressure ulcer. This allows those who are obviously not at risk to be quickly identified, preventing the need for a more detailed full assessment, which will save time in clinical practice
- a risk profile is identified for each patient (rather than a score condensed from different aspects of risk) to support care planning, with interventions selected in response to specific risk factors
- there is incorporation of the symptom of pain as a risk factor
- colour is used to aid decision-making
- there is a clear distinction between primary and secondary prevention: patients with an existing pressure ulcer or scarring from a previous ulcer are allocated to a secondary prevention and treatment pathway. This has the potential to facilitate escalation of interventions to prevent deterioration in existing pressure ulcers and promote healing
- development was based on a systematic review of the risk factor evidence and the pain cohort study
- development involved international and interdisciplinary experts in the field
- the tool was developed in partnership with service users.

Patient and public involvement in the risk assessment work package

Pressure Ulcer Research Service User Network UK members have been involved at various stages throughout this work package:

- involvement in the consensus study (with particular emphasis on the acceptability of pressure ulcer risk assessment elements for patients)
- contribution to the development of the case studies for the Risk Assessment Framework pre-test study
- reviewing the Risk Assessment Framework following the pre-test
- supporting the development of the Risk Assessment Framework clinical evaluation study, particularly relating to the development of patient information leaflets.

This project has provided some specific examples of the impact of PPI. The impact can be clearly seen in changes that were made to the Risk Assessment Framework as a direct result of PURSUN UK members' input, such as the exclusion of albumin, the inclusion of pain and a previous severe pressure ulcer and changes to the wording of the sensory perception domain. PURSUN UK members also highlighted the need to adapt the Risk Assessment Framework so that it can be used by patients and carers at home. This is being incorporated into our next programme of work.

Conclusions

The risk assessment work package comprising a systematic review of pressure ulcer risk factors, consensus study, conceptual framework development, design and pre-test and clinical evaluation led to the development and validation of a new Risk Assessment Framework, the PURPOSE-T [see http://medhealth.leeds.ac.uk/purposet (accessed July 2015)], with an underpinning risk factor Minimum Data Set.

The PURPOSE-T comprises two stages of assessment, the screening stage for all patients and the full assessment stage for patients at potential/actual risk or with an existing pressure ulcer. It facilitates the identification of a risk profile rather than a condensed score and allows patient to be allocated to a not currently at risk, primary prevention (at risk) or secondary prevention and treatment pathway (existing pressure ulcer or scarring from a previous pressure ulcer). The next stage of the development process will involve dissemination of the PURPOSE-T into routine NHS care, which will facilitate large-scale multivariable modelling and predictive validity testing, allowing refinement of the tool. The conceptual framework also provides a foundation for a programme of bioengineering and translational research to develop improved assessment techniques with greater precision for clinical use. The work package makes a key contribution to the pressure ulcer field and has the potential to directly impact risk assessment in clinical practice. The research methodologies utilised may also have a broader application to other relevant areas of health-care research.

Chapter 6 Development and evaluation of a patient-reported pressure ulcer health-related quality of life instrument

Chapter written by Claudia Rutherford, Julia M Brown, Michelle Briggs, Susanne Coleman, Carol Dealey, Elizabeth McGinnis, E Andrea Nelson, Nikki Stubbs, Lyn Wilson, Delia Muir and Jane Nixon.

Abstract

Introduction: Patient-reported outcome instruments are used to inform patient care and provide a strong evidence base for new treatments that incorporate patient perspectives. However, no PRO instruments for assessing the impact of pressure ulcers on HRQoL are available. Therefore, we aimed to (1) develop a conceptual framework of HRQoL specific to pressure ulceration, (2) develop a self-report HRQoL instrument for use with patients with pressure ulcers and (3) undertake a comprehensive evaluation of the fundamental psychometric measurement properties of the new instrument.

Methods: We used gold standard methods to develop and evaluate a new PRO instrument for people with pressure ulcers (PU-QOL) instrument. In phase 1 we developed a conceptual framework describing the impact of pressure ulcers on HRQoL using three sources: a systematic review of the pressure ulcer HRQoL literature, clinical expertise and qualitative data from 30 patient interviews. In phase 2 we developed a provisional instrument. First, we used the conceptual framework to form the basis of the PU-QOL scales. Next, we generated a pool of questions representing all outcomes from the conceptual framework. These questions were generated from the phase 1 patient interviews, from two further systematic reviews of pressure ulcer pain and existing chronic wound measures and by asking experts. The questions were then brought together to produce a draft instrument. Finally, we pre-tested the provisional instrument using mixed methods (cognitive interviews with 35 patients and Rasch measurement theory). In phase 3 we undertook psychometric evaluation in two field tests. In field test 1 we undertook item reduction and testing of scale formation; assessment of differential item functioning to determine the optimal mode of administration (Rasch measurement theory); and assessment of acceptability, scaling assumptions, reliability and validity (classical test theory) using PU-QOL data from 285 patients. In field test 2 we undertook psychometric evaluation of the item-reduced version of the instrument on PU-QOL data from an additional 229 patients, using both Rasch measurement theory and classical test theory, to test scale targeting, item response categories, item fit, response bias, acceptability, scaling assumptions, reliability and validity.

Results: Our conceptual model includes four HRQoL domains (symptoms, physical functioning, psychological well-being, social participation) divided into 13 subdomains. The final PU-QOL consists of 10 scales to measure pain, exudate, odour, sleep, vitality, mobility/movement, daily activities, emotional well-being, self-consciousness and appearance, and participation. We established that a self-administration mode is not suitable for hospital inpatients with pressure ulcers and it is therefore intended for administration following a user manual, with respondents rating the amount of 'bother' attributed on a 3-point scale. The final PU-QOL evaluation provides preliminary evidence in support of measurement reliability and validity; Cronbach's alpha values for the PU-QOL scales ranged from 0.89 to 0.97 and hypothesised correlations between PU-QOL and Short Form questionnaire-12 items (SF-12) scores ($r > 0.30$) were consistent with predictions.

Conclusions: We have identified HRQoL outcomes that are important to people with pressure ulcers and developed a conceptual framework of HRQoL and the PU-QOL instrument, reflecting the conceptual domains. The PU-QOL instrument provides a standardised method for assessing the impact of pressure ulcers and for quantifying the benefits of associated interventions from the patient perspective, thus far lacking in this area. It can be used in research with adults with any type of pressure ulcer and is suitable for all UK health-care settings. Further work is needed to provide evidence in support of score interpretation and to explore the utility of the PU-QOL in routine practice.

Introduction

Health-related quality of life

A patient's health status can be measured through various concepts, including symptomatic outcomes (i.e. pain), effect on ability to carry out daily tasks and more complex concepts such as HRQoL. HRQoL is a multidimensional construct that encompasses four primary domains: psychological, physical, social and role functioning and issues relating to well-being.[205,206] Assessment of HRQoL is no longer just a relevant end point of clinical trials but is often carried out in routine clinical practice and is considered essential to understanding the quality of health care.[207] HRQoL data provide information about the impact of a specific disease and subsequently increase awareness of, and the ability to address, the needs and concerns most important to patients. As such, assessment of HRQoL is particularly relevant in disease areas in which there is a significant impact on HRQoL and a significant treatment burden, such as chronic wounds.

Impact of pressure ulcers on health-related quality of life

The impact of pressure ulcers on HRQoL is substantial, although few studies contain empirical data to substantiate this assumption.[9] Our pre-programme systematic review[9] identified that the majority of work to date has been mainly qualitative and that pressure ulcers severely compromise patient functioning: they can affect sleep, rehabilitation, mobility and psychological, physical and social aspects of patients' lives.[34,208,209] They also cause patients substantial pain. However, the pain is often underestimated by health-care professionals:[210] patients described how their ulcer-related pain was largely unrecognised by health-care professionals, how their reports of pain were ignored and how their ulcer-related pain was rarely formally assessed,[9] findings consistent with those from the severe pressure ulcer study (see *Chapter 4*).

Health-related quality of life not only is related to the presence of a pressure ulcer but also is affected by the treatments that patients undergo to either prevent or treat a pressure ulcer. Because of the complexity of pressure ulcers, health-care professionals face the challenge of providing effective preventative and treatment interventions. The choice of intervention depends on the purpose, for example pressure damage prevention using pressure-reducing/-offloading devices and repositioning, skin protection from moisture or wound treatments to promote healing. NHS practice guidance is focused on identifying patients at risk through risk assessment of all patients on admission to acute hospital and community nursing services (see *Chapter 5*), implementing preventative care (e.g. specialist mattresses, turning, skin care) and using interventions to halt damage and promote healing (e.g. mattresses, dressings, nutritional supplements).[1,11,14,15,211] However, these interventions can affect patient functioning and cause significant treatment burden.[33] For example, the frequency and regularity of dressing changes may affect a patient's daily routine, increase fatigue, restrict mobility and cause additional pain or discomfort.

Our pre-programme work has identified factors within the wider health-care context that may contribute to reduced or improved HRQoL, such as satisfaction with health care received, inconsistencies in the health care provided (i.e. different methods between nurses, wards and/or hospitals) and the relationship between patient and health-care provider.[9,10] These contributory factors relating to service organisation were also evident from the severe pressure ulcer study (see *Chapter 4*). Assessment of HRQoL and other contributory outcomes can facilitate patient–health-care provider communication and provide information required for effective health-care planning and ulcer management. In addition to improving patient health care, assessment of HRQoL can be important for indicating how satisfied patients are with the health care received, indicators that are important for treatment and health-care effectiveness.

Measuring health-related quality of life in people with pressure ulcers

Assessment of HRQoL is considered subjective in nature and therefore best measured by directly asking the person involved through the use of PRO instruments or rating scales. The best PRO instruments are designed to probe people in a structured, formal way to give reproducible, meaningful, quantitative assessments from a personal perspective of how they feel and function.[212] PRO instruments may be generic, designed to measure concepts that are relevant across different diseases, outcomes, treatments and populations, or disease/condition specific, designed to assess the impact of a specific disease or condition on HRQoL, with the goal of detecting clinically important changes.[213]

The use of PRO instruments has become increasingly important in many disease areas[214,215] and there has been a growth in instruments to evaluate HRQoL in some chronic skin conditions. However, established PRO instruments are currently not available for use with patients with pressure ulcers.[216] PRO instruments are used to inform and monitor the performance of patient care and health-care delivery and are important for providing a strong evidence base for new treatments that incorporate patient perspectives and cost-effectiveness. Cochrane reviews highlight the lack of reliable evidence for the clinical effectiveness of a majority of pressure ulcer treatments.[20] Further, few studies in this field include PROs as study outcomes[9] and national and international prevention and treatment guidance is not mandated.[1,15] When HRQoL outcomes have been assessed, generic or chronic wound-specific measures have been used.[216] However, despite common conceptual domains between pressure ulcer and chronic wound HRQoL models, existing PRO instruments do not adequately represent pressure ulcer-specific HRQoL outcomes (e.g. content differs at the subdomain and item level; important components such as issues stemming from treatments and symptoms, mobility, sleep, embarrassment and physical appearance are not well represented),[216] questioning their appropriateness for use in pressure ulcer research. Moreover, assessment of outcomes in clinical trials of pressure ulcer intervention effectiveness either has been limited to conventional clinical outcomes (i.e. prevention or healing) or has used limited, inappropriate (i.e. not fit for purpose) or inadequately validated instruments.[9,72] Importantly, clinical decision-making is not informed by high-quality studies based on patients' perspectives and cost-effectiveness.

We need a systematic way of considering (1) patients' priorities for interventions and (2) health economic evaluation (see *Chapter 7* for work to derive a preference-based measure for use in cost–utility analysis). A PRO instrument specific to pressure ulcers could facilitate clinician–patient communication, shared decision-making and training of new staff; identify and prioritise patient problems and preferences; monitor changes or outcomes of treatment; measure the performance of health-care providers; and facilitate clinical audit.[217–220]

Aim and objectives

The principal aim of this work package was to develop a PRO measure of HRQoL specific for people with pressure ulcers, the PU-QOL instrument. This would provide a standardised method for evaluating patients' needs and self-reports of the impact of pressure ulcers and their treatment on HRQoL.

Specific objectives were to:

1. identify HRQoL outcomes relevant to patients with any category of pressure ulcer and the relative ulcer burden
2. develop a PRO measure of HRQoL specific to pressure ulcers that is acceptable, reliable and valid and suitable for use in the UK.

Research overview

Several sequential pieces of reseach were undertaken to develop and evaluate the PU-QOL instrument (*Figure 25*):

1. phase 1: conceptual framework development[10,221] comprising:
   - pre-programme systematic review[9] (see *Pre-programme systematic review overview*)
   - in-depth qualitative interviews[10,221] (see *Qualitative study*)
   - expert opinion[10,221] (see *Expert opinion*)

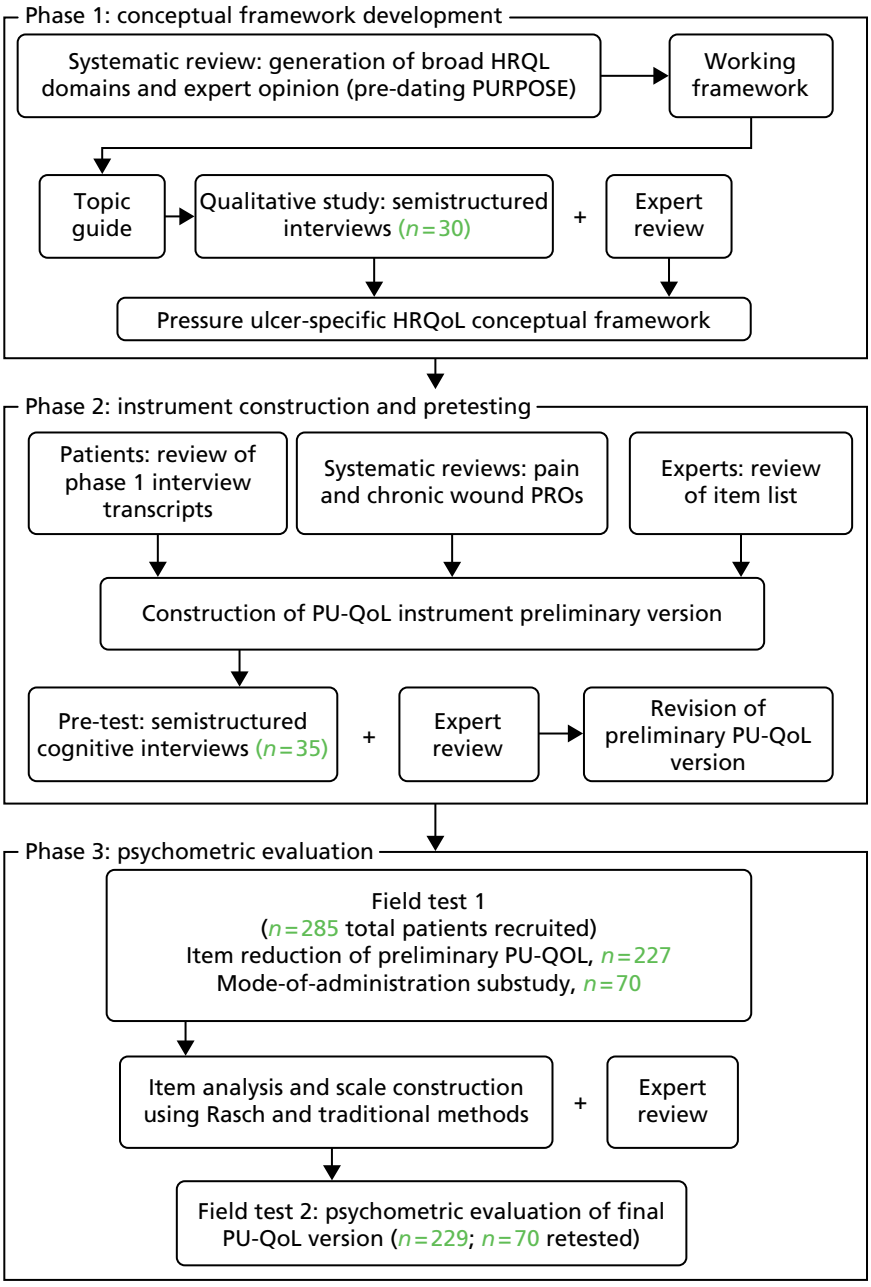

FIGURE 25 Flow diagram of the research undertaken to develop and evaluate the PU-QOL instrument.

2. phase 2: instrument construction and pre-testing comprising:

    i. item generation:[35,216]

        – review of patient interview transcripts from phase 1b (see *Item generation from patients*)
        – systematic review of existing chronic wound instruments literature[216] (see *Existing chronic wound instruments: systematic review*)
        – systematic review of pressure ulcer-related pain literature[36] (see *Pressure ulcer-related pain: systematic review*)
        – item generation from experts (see *Item generation from experts*)

    ii. preliminary PU-QOL construction (see *Preliminary PU-QOL construction*)
    iii. pre-testing through semistructured cognitive interviews with patients[222] (see *Pre-testing*)

3. phase 3: psychometric evaluation in two parts:

    i. field test 1: item reduction and scale formation; mode of administration substudy (see *Field test 1 and mode of administration substudy*); acceptability, scaling assumptions, reliability and validity [classical test theory (CTT)]
    ii. field test 2: a comprehensive psychometric evaluation of the final version, including scale targeting, item response categories, item fit, response bias, acceptability, scaling assumptions, reliability and validity, using both Rasch and traditional psychometric methods[223] (see *Field test 2: final psychometric evaluation*).

International PRO instrument guidelines and criteria were consulted to ensure high quality and standardisation for PU-QOL development.[192,212,224,225] Collaboration was sought from members of EPUAP and from 29 acute and primary care NHS trusts around the UK.

Phase 1: conceptual framework development

Various parts are reprinted from *Int J Nurs Stud*, vol. 47, Gorecki C, Lamping DL, Brown JM, Madill A, Firth J, Nixon J. Development of a conceptual framework of health-related quality of life in pressure ulcers: a patient-focused approach, pp. 1525–34, 2010,[221] with permission from Elsevier.

When developing a new PRO instrument, the construct intended for measurement (in this case quality of life associated with pressure ulceration) needs to be clearly defined and the content (items) needs to reflect the construct. The first phase of the project involved developing a conceptual framework, by tapping into three sources. First, a systematic review and narrative analysis of the HRQoL outcomes literature relevant to pressure ulcers was undertaken (work predating the programme).[9] The review generated HRQoL issues, which were grouped into HRQoL domains, formulating a working conceptual framework. Second, in-depth qualitative interviews were undertaken with a sample of patients with pressure ulcers. From the information obtained from the patient interviews and the third source, expert opinion, a final conceptual framework was produced.

Pre-programme systematic review overview

We undertook a systematic review (pre programme) of both the qualitative and quantitative pressure ulcer and HRQoL literature to identify the impact of pressure ulcers and associated interventions on HRQoL.[9] We included studies describing the impact on HRQoL from direct patient reports. From 31 studies, including 2463 participants with pressure ulcers aged between 17 and 96 years, we extracted 293 findings, which were divided into 46 categories and 11 themes. Our working conceptual framework consisted of HRQoL themes (physical, social and psychological impact, symptoms, general health) and other impacts of pressure ulcers (health-care professional–client relationships, need for vs. effect of interventions, impact on others, financial impact, perceived aetiology, need for knowledge).[9] Importantly, the systematic review highlighted

that pressure ulcers severely impact on patients' HRQoL and that there was no PRO instrument available to assess pressure ulcer-specific HRQoL outcomes.

Qualitative study

An important consideration when developing PRO instruments is conceptualisation and content of the instrument. Developers of disease-/condition-specific PRO instruments often utilise both top-down (e.g. literature review) and bottom-up (e.g. qualitative data) approaches to develop the conceptual framework to ensure that those aspects of HRQoL that are most important to patients with the underlying condition are reflected. Having used the top-down approach (see *Pre-programme systematic review overview*) we then undertook a qualitative study (see *Appendix 38* for the study protocol) utilising the bottom-up approach.

Aim

The aim of this study was to undertake in-depth qualitative interviews with a sample of patients with pressure ulcers. The information obtained would be used to develop a conceptual framework of HRQoL specific to pressure ulcers. Specific objectives were to:

1. identify HRQoL outcomes relevant and important to patients with grade 1, superficial and severe pressure ulcers
2. identify whether HRQoL outcomes for patients with grade 1, superficial and severe pressure ulcers are the same in relation to the impact of interventions
3. gain insight into the relative ulcer burden and what it is like to live with a pressure ulcer.

Methods

Design

Top-down (literature review) and bottom-up (qualitative data) approaches were combined to develop the conceptual framework. The top-down approach involved developing a working conceptual framework of HRQoL in pressure ulcers, based on a systematic review of the quantitative and qualitative pressure ulcers and HRQoL literature.[9] The bottom-up approach involved further qualitative work to elicit information pertaining to the impact of pressure ulcers on HRQoL and specific domain components. A multidisciplinary expert group, including seven tissue viability nurse specialists, a chronic pain specialist and five outcome methodologists (see *Acknowledgements*), reviewed the qualitative results and final conceptual domains.

Participants

Eligibility Patients from both acute and primary care were included because of the high pressure ulcer prevalence in both settings and the need to obtain perspectives from people in both settings as interventions can differ between settings. Adult patients with a pressure ulcer of any severity,[1] duration or location or a pressure ulcer that had recently healed (within 3 months) were included if they were aged $\geq$ 18 years, from a hospital, rehabilitation or community setting and under the care of a tissue viability nurse specialist and were able to reflect on and share their experience and provide informed consent to participate. Patients were excluded if they did not currently have a pressure ulcer or one that had healed within the previous 3 months or were unconscious, confused, cognitively impaired or unable to speak English.

Sampling A purposive sampling method was devised, with sampling of patients targeted to key factors to reflect the range and diversity of the target population, including age ($<$ 70 years and $\geq$ 70 years), ulcer severity (superficial and severe[129]) and location (torso and limb sites) and health-care setting (hospital and community). A minimum of five patients per key factor were consecutively sought and found.[221]

Recruitment and data collection

Eligible patients were identified and approached to participate by members of the tissue viability teams at participating hospitals and community services, who provided information (see *Appendix 39*) about the rationale, design and personal implications of the study and the 'agree to be contacted by the researcher' form (see *Appendix 40*). Following information provision, patients had as much time as they needed to

consider participation. After receiving a signed agreement to be contacted, the researcher (CG) carried out an interview at the patient's home or hospital ward, which was audio recorded and transcribed verbatim.

We conducted individual face-to-face semistructured interviews, guided by an interview schedule (e.g. questions to confirm or refute the importance of the working framework domains), open-ended questions to elicit relevant new information (e.g. 'Is there anything else that you want to add about how your pressure ulcers may have impacted you?') and clarifying questions (e.g. 'Do you think [that] is only because of your pressure ulcer or possibly resulting from a combination of things?) to ensure that issues reported were in fact the result of pressure ulceration (see *Appendix 41*). The provisional HRQoL domains were revised as new information emerged from the data, refining the working framework deductively, and were incorporated into discussion in subsequent interviews to confirm the importance of new HRQoL issues.

Data analysis

First, the researcher read the transcripts while listening to the recording to confirm the accuracy of transcription and to obtain an overview of the data collected. Any first impressions and interpretations were noted, including thoughts about the main HRQoL domain components, general feelings about the interview and audio cues from the patient that would be lost in transcription. Preliminary analysis was carried out after the first three patients had been interviewed to assess whether the interview schedule's HRQoL domains were consistent with the emerging themes and to identify any gaps in information. Then, two researchers (CG, JF) conducted thematic content analysis manually of textual data from the first four interviews, identifying HRQoL issues within the transcripts and coding to a provisional coding schema developed using a combined inductive (codes arising from transcripts) and deductive (codes developed from the interview schedule) approach. The provisional coding schema was refined during subsequent stages of the analysis; data collection and coding were conducted iteratively in multiple rounds of interviews so that subsequent data collection was informed by earlier coding and confirmed in later interviews.

Expert opinion

Health-related quality of life components that emerged from the patient interviews were reviewed by a multidisciplinary expert group (see *Acknowledgements*). Any issues mentioned infrequently were discussed and those that were agreed not to be clinically relevant were either excluded or consolidated with related components (e.g. various negative emotions such as irritated and distressed were consolidated with 'negative mood changes') rather than being retained as separate components in the conceptual framework.[221] Following data analysis, the group reviewed the final conceptual framework with the view towards making a distinction between components that addressed the impact of pressure ulcers on HRQoL and other contributory factors that may affect HRQoL.[10]

Ethical approval

The study was approved by the North West Research Ethics Committee prior to data collection (reference number 07/H1010/60).

Results

Thirty-two patients with pressure ulcers from seven acute and primary care settings in England and Northern Ireland during December 2007 to October 2008 consented to participate. However, two patients were recruited twice and were not interviewed and so the final sample included 30 interviews (a record of those approached to participate and refusals was not made). Participants ranged in age from 22 to 94 years (mean age 62.2 years), 18 (60%) were male and 19 had other chronic conditions (e.g. eight had a spinal cord injury and three had multiple sclerosis). Patients represented different settings ($n = 17$ hospital or rehabilitation; $n = 13$ community), ulcer severity ($n = 12$ superficial; $n = 15$ severe; $n = 3$ mixed severity), numbers of pressure ulcers ($n = 13$ had more than one ulcer), ulcer duration (few days up to 4 years) and sites ($n = 15$ sacrum; $n = 14$ heel; others on the lower back, buttocks, ankles, hips, back of head and elbow).[221]

We identified both HRQoL outcomes and contributory factors that affect pressure ulcer-related HRQoL. Contributory factors included six experience-of-care and 10 individual patient factors. Adults with pressure

ulcers have concerns about treatment and wound management, treatment burden, communication difficulties, their ability to cope with functional limitations, poor support networks and other health problems and comorbidities.[10] However, as the intention was to develop a HRQoL instrument, a distinction between HRQoL outcomes and contributory factors (such as motivation and satisfaction with health care received) that may affect HRQoL was made (see *Expert opinion*), resulting in a defined, conceptualised and operationalised pressure ulcer-specific HRQoL conceptual framework.

The pressure ulcer-specific conceptual framework consists of four domains and 13 subdomains: symptoms (pain and discomfort, exudate, odour), physical functioning (mobility, daily activities, general malaise, sleep), psychological well-being (mood, anxiety and worry, self-efficacy and dependence, appearance and self-consciousness) and social functioning (isolation, participation)[221] (*Figure 26*). This study provides qualitative evidence on HRQoL components that are important from the perspective of patients with pressure ulcers, an essential step when developing new PRO measures. The conceptual framework provides the basis for the development of the new pressure ulcer-specific measure of HRQoL.

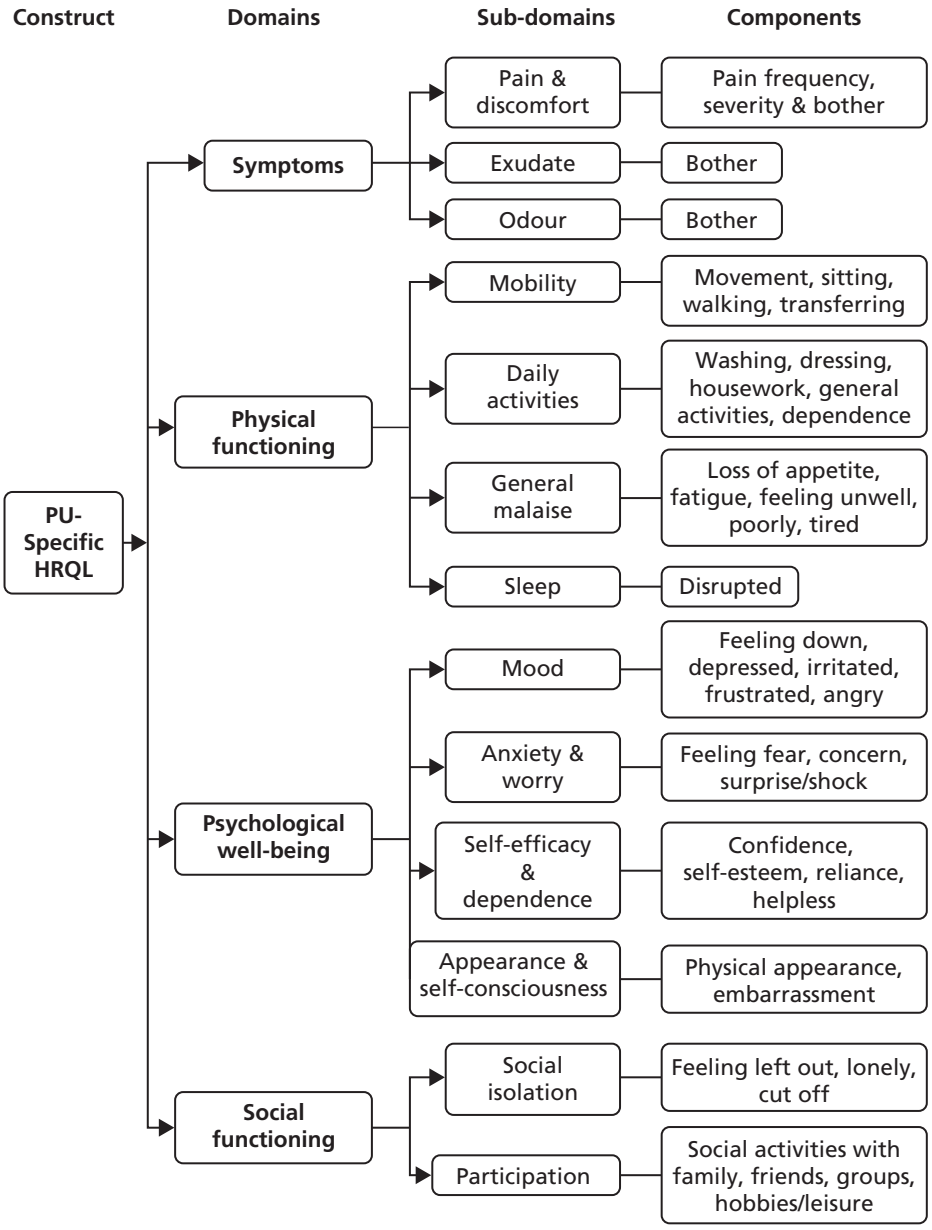

FIGURE 26 Pressure ulcer-specific HRQL conceptual framework. PU, pressure ulcer. Reprinted from *Int J Nurs Stud*, vol. 47, pp. 1525–34, 2010, Gorecki C, Lamping DL, Brown JM, Madill A, Firth J, Nixon J. Development of a conceptual framework of health-related quality of life in pressure ulcers: a patient-focused approach,[221] with permission from Elsevier.

Phase 2: item generation, instrument construction and pre-testing

Various parts are largely reprinted from *J Pain Symptom Manage*, vol. 42, Gorecki C, Closs J, Nixon J, Briggs M. Patient-reported pressure ulcer pain: a mixed methods systematic review, pp. 443–59, 2011,[36] with permission from Elsevier; and from *Int J Nurs Stud*, vol. 51, Gorecki C, Lamping DL, Alvari Y, Brown JM, Nixon J, Patient-reported outcome measures for chronic wounds with particular reference to pressure ulcer research: a systematic review, pp. 157–65, 2014,[216] with permission from Elsevier.

The second phase of this project was the development of the PU-QOL instrument. Three sources were utilised to generate the list of candidate items for the instrument: patient interview transcripts (see *Item generation from patients*); systematic reviews of the pain literature and existing chronic wound PRO instruments (see *Item generation from existing instruments and pressure ulcer pain literature*); and experts in the field (see *Item generation from experts*). The item list was used to construct a preliminary version of the PU-QOL (see *Preliminary PU-QOL construction*), which was pre-tested with a sample of patients with pressure ulcers using mixed methods [cognitive interviews and Rasch measurement theory (RMT) (see *Pre-testing*)]. Based on information obtained from patients and expert opinion, the pre-test version was revised accordingly.

Item generation from patients

Item generation involved developing an exhaustive list of potential items (item pool) for each domain within our conceptual framework. Content (patient words verbatim) from the phase 1 patient interviews (see *Qualitative study*) was used to generate items. All content was grouped into HRQoL domains, with each domain comprising a number of items describing slightly different components. We took the inclusive approach retaining all content if reported more than once. Interview data were an excellent source for generating items as items using patients' words and representing variable components across the broad spectrum of pressure ulcer-specific HRQoL outcomes were identified.

Item generation from existing instruments and pressure ulcer pain literature

We undertook two systematic reviews, first, to review generic, pressure ulcer-specific and chronic skin wound-specific PRO instruments used to assess HRQoL in patients with pressure ulcers or other similar chronic skin wounds[216] and, second, to review patient reports of pressure ulcer-associated pain, descriptions of the pain experience and the impact on patients' lives.[36]

Existing chronic wound instruments: systematic review

Despite the impact on HRQoL, no research has been undertaken to determine the availability of PRO instruments, either generic or condition specific, and their suitability for use in pressure ulcer research. We developed a pressure ulcer-specific HRQoL conceptual framework (see *Qualitative study*). The conceptual framework provides a structured and formal framework against which the content of available PRO instruments can be assessed.

Aim

The aim of the systematic review was to identify generic, pressure ulcer-specific and chronic skin wound-specific PRO instruments used to assess HRQoL in patients with pressure ulcers or other chronic skin wounds and determine how useful or appropriate they are, based on their content, for use with patients with pressure ulcers in assessing HRQoL outcomes.

Methods

Study eligibility Studies of any design were included if PRO measures were used to assess HRQoL or related concepts in adult patient populations presenting with any grade of pressure ulcer or other chronic wounds, from hospital, rehabilitation or community health settings within Europe, North America or Australia. Studies were excluded if (1) HRQoL was assessed by the health-care provider or proxy

(i.e. not patient reported); (2) they used an instrument intended primarily for other medical conditions, in which pressure ulcers are a secondary outcome (e.g. Life Situation Questionnaire); (3) they used an instrument assessing mediating or contributory outcomes only (e.g. Inventory of Socially Supportive Behaviours, personality scales, locus of control, Coping Response Inventory, Mini Mental State Examination for screening cognition); (4) HRQoL was assessed using a single-item rating scale [i.e. visual analogue scale (VAS)]; or (5) they were limited to paediatric populations or wounds caused by trauma (e.g. burns). Abstracts from conference proceedings were excluded unless additional information was provided by the authors[216] (see *Appendix 42* for data sources and search strategies).

Study selection and quality assessment One researcher screened abstracts for relevance. Studies assessed as potentially relevant or studies whose relevance was ambiguous were obtained in full for further scrutiny. Two researchers independently assessed potentially relevant studies against the inclusion criteria. Studies that did not meet the inclusion criteria were excluded from further analysis.[216]

Measures without evidence of any development or validation process (i.e. ad hoc instruments with no formal reliability or validity testing) were excluded. Additional quality components were not used as a threshold for the inclusion of instruments as the intention was to provide a descriptive summary of the content domains of existing instruments used to assess HRQoL in patients with pressure ulcers and other chronic wounds. However, empirical evidence for reliability and validity was a minimum requirement for inclusion of PRO instruments.[216]

Data extraction Data were independently extracted by two reviewers. We cross-checked data extraction for errors, omissions and consistency between extractions. Disagreements or discrepancies were discussed between the two researchers and confirmed with a psychometrics expert (DL). We had intended to extract data on the development and evaluation of PRO instruments to allow the appraisal of the measurement properties[216] for PRO instruments that had at least 75% of pressure ulcer-specific content (at both domain and item level) and no more than 25% of non-relevant content. As none of the identified measures met these criteria, the measurement properties were not extracted and assessed.

Data synthesis Our analysis systematically determined the extent to which PRO instruments covered the pressure ulcer-specific conceptual framework (see *Figure 26*).[216] Items from identified instruments were mapped to the conceptual framework to determine content of relevance to pressure ulcers. Those considered relevant could be included in the item pool.

Results

Three generic and 14 chronic wound instruments were identified but no pressure ulcer-specific instruments (*Figure 27*).[216] None of the available instruments cover all HRQoL domains that are important in pressure ulcers. One condition-specific instrument, the Venous Leg Ulcer instrument, matched most closely conceptually, but failed to represent three important domains and contained items not specific to pressure ulcers.[216] Although a potentially valuable source for generating items, few items were assessed as pressure ulcer specific (i.e. they were worded to assess the impact of other conditions and not specifically the impact of pressure ulcers) or were items already generated from patient reports.

Pressure ulcer-related pain: systematic review

Pressure ulcers can cause patients considerable pain and discomfort; however, little is known about how pressure ulcer pain affects patients' everyday lives.

Aim

The aim of this systematic review was to identify and synthesise all research that included verbal patient reports of pressure ulcer-associated pain, including descriptions of the pain experience, intensity and quality and impact, to interpret the complexities of the pain experienced from pressure ulcers. Specific objectives were to describe specific characteristics of pressure ulcer pain and determine how it affects patients' lives.[36]

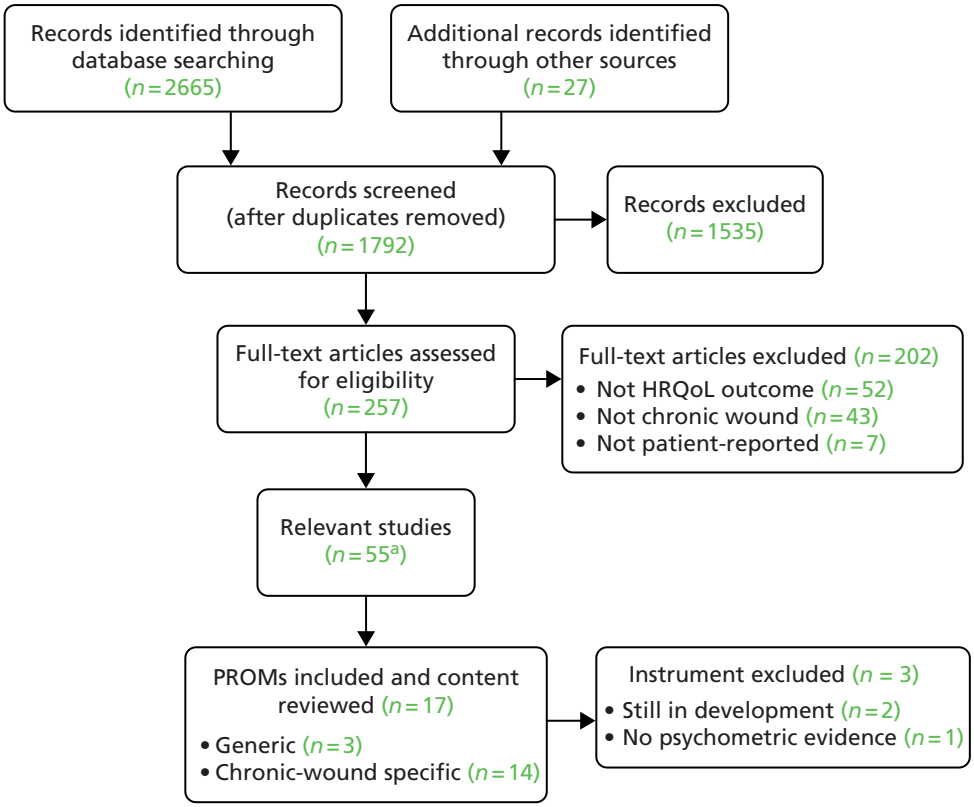

FIGURE 27 Flow of studies: existing instrument systematic review. a, Duplication of instruments across studies. PROM, patient-reported outcome measure. Reprinted from the *International Journal of Nursing Studies*, vol. 51, pp. 157–65, 2014, Gorecki C, Lamping DL, Alvari Y, Brown JM, Nixon J, Patient-reported outcome measures for chronic wounds with particular reference to pressure ulcer research: a systematic review,[216] with permission from Elsevier.

Methods

Study eligibility Studies were included if the study sample consisted of adult patients with any category of pressure ulcer from any setting with any existing comorbidity and the study used qualitative methods to obtain patient reports of their experience of pressure ulcer pain. Studies using mixed-method designs were included only if pressure ulcer-specific findings were reported separately from mixed wound findings or quantitative methods to assess pain used existing validated outcome measures in which pain descriptors were available. Studies that used patient-reported HRQoL instruments were considered if a pain scale was included and the results were reported. Studies were excluded if the study sample consisted of those with mixed wounds, pressure ulcer-associated pain was not patient reported (i.e. proxy assessment) or data were collected using ratings or a VAS to obtain pain severity scores. No upper age, gender or language restrictions were applied (see *Appendix 42* for data sources and search strategies).[36]

Study selection and quality assessment Study selection methods were consistent with those described in *Existing chronic wound instruments: systematic review*.

Individual quality components of study methodology were not used as a threshold for the selection of primary studies. We included all available data but assessed the appropriateness of each study by making a judgement about whether a study used appropriate methods for addressing our review questions and for ensuring that findings about the pressure ulcer pain experience were indeed from the patient perspective (e.g. whether data collection methods were appropriate for helping patients express their views and how pressure ulcer pain affects them).[36]

'Data extraction and synthesis Two reviewers independently extracted findings in the form of direct patient quotes and allocated findings to defined categories. A category was determined by grouping common findings (i.e. findings that reflected similar phenomena or variables). Categories that were sufficiently similar in meaning were generated into synthesised themes. Synthesis of findings and categories was reviewed by three reviewers until consensus. Any descriptions relating to pressure ulcer-associated pain, including descriptions of the pain experience, intensity, quality and impact, could be included as items.'[36]

Results

'Ten studies were included: six qualitative and four quantitative studies (*Figure 28*). These included 108 adults with pressure ulcers. We produced a biopsychosocial model of the pressure ulcer pain experience, including five domains: communicating the pain, feeling the pain, impact of pain, self-management and professional management. The findings of the review suggest that, to achieve the best possible outcomes that are important to patients, improved communication of pain experienced between the individual and health-care professional and across disciplines, interventions to help control or reduce pressure ulcer pain, patient-centred concerns and systemic barriers need to be considered when managing pressure ulcers to ensure more effective pressure ulcer pain management in the future.'[36] These findings are consistent with those from the severe pressure ulcer study (see *Chapter 4*).

With regard to potential items, similar to the existing instrument systematic review, pain-related issues had already been identified from patient reports and no new descriptors were added to the item pool.

Item generation from experts

As patients with pressure ulcers receive specialist care from health-care professionals who have a vast range of experience in treating patients with pressure ulcers and therefore probable insight into patients' experiences, a clinical expert group reviewed the item pool generated from patient interviews. The group consisted of three community and acute care tissue viability nurse specialists (LW, NS, EM), three nurses with extensive experience undertaking pressure ulcer research (JN, EAN, CD), one chronic wound pain specialist (MB) and one nurse with experience of health-care policy development (SC) (see *Acknowledgements*). Items were grouped by domains and the focus of the review was on item grouping and relevance, content and wording and clinical importance. Items with similar content were highlighted and the accuracy of domain

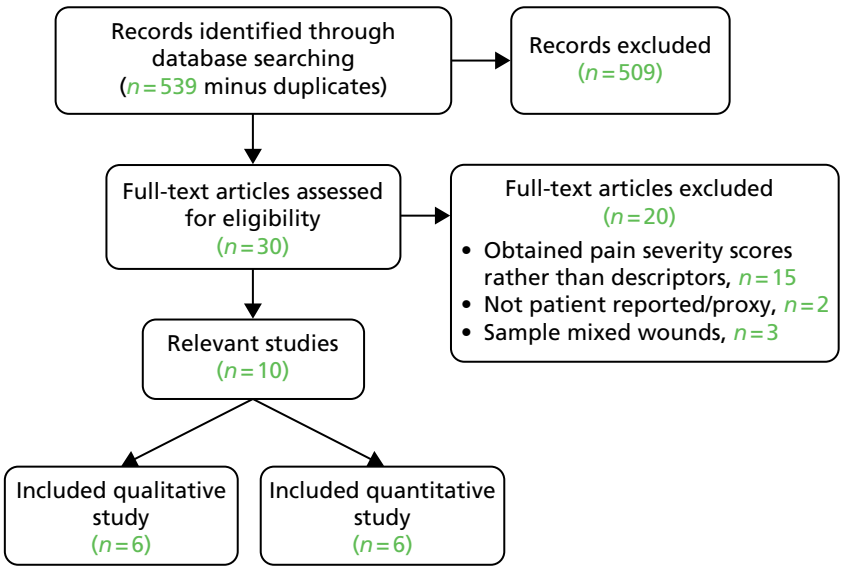

FIGURE 28 Flow of studies: pain systematic review.

categorisation (item grouping) was discussed. Additional items were added if necessary. Items were retained if they were considered clinically relevant, not too similar (redundant items were combined or removed) or to pertain to HRQoL (not measuring other constructs such as personality or satisfaction). Final item elimination decisions were based on consideration of item problems in combination.

At this stage an important conceptual decision was made to include pressure ulcer symptoms of pain, exudate and odour into the pressure ulcer-specific model. These symptoms are important consequences of having a pressure ulcer but initially were not considered HRQoL outcomes and were therefore excluded from the original item pool. Counting the frequency or assessing the intensity of symptoms may not be an adequate measure of HRQoL,[226] but the impact of symptoms and the meaning that they have for individuals is an important aspect of HRQoL assessment and therefore is considered important for inclusion in a pressure ulcer-specific PRO instrument. Patient comments pertaining to these outcomes were identified in the qualitative work and items were added to represent these symptoms. The amended item pool and content mapping were reviewed by a group of seven health outcome methodologists (see *Acknowledgements*), who focused on the constructs measured (e.g. whether or not items for each domain were representative of the construct being measured) and item wording (i.e. whether any items were confusing, ambiguous, double-barrelled). The process of item generation resulted in an initial pool of 118 items (see *Appendix 43*).

Construction of the preliminary Pressure Ulcer Quality of Life tool

The development of the preliminary PU-QOL instrument involved careful stepwise construction with consideration of the design, layout and instructions, framing of questions, response format and recall period to ensure that the way that the PU-QOL was presented was tailored to the characteristics of patients with pressure ulcers (i.e. understood by and relevant to the intended population).

Instructions, design and layout

Consistent with recommendations,[227] general information pertaining to what the PU-QOL instrument is about and instructions about how questions should be answered were placed at the beginning of the instrument. Instructions specific to individual questions were placed close to the relevant question. Instructions were brief and clear and bold font was used to highlight important components (e.g. 'during the past week' and 'tick all that apply'). A statement ensuring confidentiality was included to encourage accurate reporting.

The PU-QOL instrument was designed as a double-sided A4-size booklet on white paper. Font size 12 was chosen as respondents are largely elderly people with some visual impairment. Questions were grouped into item sets (scales; see *Framing of questions*) and numbered, not crowded or split between two pages, with horizontal response formats (see *Response options*) attached, and ended with a thank you.[227]

Framing of questions

The US Department of Health and Human Services Food and Drug Administration (FDA) guidance for developing PRO instruments[212] recommends that items should adequately cover important conceptual domains, relate to the instrument's objectives, use words that are familiar to patients and not be confrontational, upsetting or ambiguous. These recommendations were considered when constructing the PU-QOL instrument to ensure clearly formulated and precise items.

Operationalisation

The item pool ($n = 118$) was transformed into scales through a process known as operationalization, in which logically related items are grouped or blocked into scales based on their conceptual meaning to represent coherent clinically meaningful constructs.[225] Each scale represented one of the 13 subdomains within the pressure ulcer-specific HRQoL conceptual framework (see *Figure 26*) and produced a scale score rather than an overall total score. The intention was to enable the monitoring of changes within patients on these 13 outcomes rather than a global HRQoL change.

Item stem

As the PU-QOL is a condition-specific instrument, the item stem had to be worded in a way that focused patients' thinking towards their pressure ulcer so that any bother attributed related to pressure ulcer impact rather than impact from other health problems that the patient might have (i.e. the item stem needed to be salient to people with pressure ulcers rather than relating to overall health status). This was considered important as people who develop pressure ulcers usually have a multitude of health problems or comorbidities that may affect the same outcomes that pressure ulcers affect, such as pain. The item stem for each question was, 'During the past week, because of your pressure ulcer, how much were you bothered by . . .', which was followed by the item content (e.g. feeling uncomfortable).

Response options

The Likert-scale response method is commonly used in PRO measurement and was the chosen method for the PU-QOL instrument. When constructing Likert scales the number of response categories to use and how they should be labelled needs to be considered.[212] The response option descriptors chosen for the PU-QOL instrument relate to the amount of bother attributed (e.g. 'How much have you been bothered by . . .?') rather than the frequency of the outcome (e.g. a symptom might be frequent but might not necessarily be bothersome). 'Bother' was a term that was frequently used by patients during the qualitative interviews (see *Qualitative study*). Both response formats (frequency of the problem and amount of bother attributed) were presented to participants during pre-testing. Each item uses four discrete response options scored with successive integer scores (e.g. 0 = no bother at all to 3 = a lot of bother). These imply a continuum of increasing impact (bother), from less (no bother) to more (a lot of bother). This assumption was tested by examination of threshold ordering in subsequent testing (see *Phase 3: field testing*).

Time frame

Important disease changes/progression and memory error (recall bias) need to be considered when choosing a time frame. A recall period of the past week was chosen on clinical grounds, as changes in pressure ulcer severity and symptomology often occur over days and thus a longer recall period would risk not capturing relevant changes in HRQoL. Events that occurred over a month ago may no longer be relevant or may have been resolved or treated.

Mode of administration

With regard to mode of administration there is essentially a choice between interviewer administered (i.e. face-to-face, telephone) and patient self-completed (e.g. postal survey, during clinic visit). Each method has its advantages and disadvantages and the current evidence is inconsistent in differentiating the superiority of one method over the other in terms of quantity and quality of response.[228] We considered that patients with pressure ulcers (i.e. acutely ill, elderly) may have difficulty with self-completion, but as the PU-QOL instrument is intended for pressure ulcer intervention effectiveness research, and there is cost–benefit associated with self-completion methods in clinical trials that require large samples,[229] the decision was made to develop a self-completed version in the first instance. The suitability of this method was determined during field test 1 (see *Field test 1 and mode of administration substudy*).

Pre-testing

Pre-testing is key in PRO instrument development. We undertook a pre-test study to evaluate patients' understanding of the items, instructions, response options and recall period, determining whether readability was appropriate for the target population and confirming the completeness of concepts covered by items[212] (see *Appendix 44* for the study protocol).

Aim

The aim of this study was to pre-test the preliminary PU-QOL version using cognitive interviewing and RMT methods to identify and resolve problems with layout, time frame, response options, framing of items and administration mode. The study was also designed to determine whether or not readability was appropriate for patients with pressure ulcers and confirm content (i.e. the need for additional items or elimination/rewording of other items) prior to formal psychometric evaluation,[222] hence it being described as 'pre-testing'.

Methods

Design

Mixed methods were used to pre-test the preliminary PU-QOL tool. The intention was to identify and resolve any problems with the way in which the PU-QOL tool was constructed, by comparing RMT[230] findings with the findings from cognitive interviews for consistency.[222] The intention was to reduce respondent burden and decrease data errors and non-response because of poor design and layout and unclear, misunderstood or irrelevant items to ensure that the PU-QOL was relevant to and understood by people with pressure ulcers.

Participants

Eligibility Adult patients from acute and primary care settings were included if they had a pressure ulcer of any severity,[1] duration or location; were aged ≥ 18 years; were from a hospital, rehabilitation or community setting; and were able to read and write in English. Patients without a pressure ulcer or who were unconscious, confused, cognitively impaired, unable to speak English or deemed ethically inappropriate to approach (e.g. death was imminent) were not eligible.

Sampling The sampling method for the pre-test was consistent with that detailed in phase 1 (see *Qualitative study*, *Sampling*).

Recruitment and data collection

The recruitment method for the pre-test was consistent with that detailed above in phase 1 (see *Qualitative study*, *Recruitment and data collection*; see also *Appendix 45* for the patient information leaflet and consent form).

Structured face-to-face cognitive interviews were undertaken to gain an understanding of how patients interpret and understand individual questions (i.e. whether questions are understood as intended) and produce their answers.[195] Emphasis was on comprehension (i.e. clarity, language), retrieval from memory and response judgements (i.e. frequency judgements, logic decisions). Interviews were conducted in patients' homes, clinics or wards, as determined by the each patient's circumstances at the time of interview.

Two interviewing techniques were employed; however, the first three participants who were asked to think aloud (spontaneous conversation) while completing the PU-QOL reported that the method made completion difficult. Therefore, the remaining participants completed the preliminary PU-QOL instrument without researcher assistance. They were instructed to flag/mark items that they found confusing, difficult to understand, upsetting/intrusive or annoying while completing the PU-QOL and to consider the format, design and response options. The preliminary version contained 118 items and took around 22 minutes to complete. Many items were similar, with slight variations in wording; however, these were retained and presented to patients for consideration.

Following completion, the researcher (CG), guided by a standard set of questions and probes (see *Appendix 46*), sought to elicit the cognitive processes employed by patients while completing the PU-QOL instrument. Patients were asked to give feedback on their understanding of each question and associated response categories and instructions and to verbalise how they had gone about producing their answers, with particular emphasis on retrieval from memory and subsequent judgements and decisions. During debriefing interviews the researcher took notes, fed back to patients to ensure comprehension of responses and reviewed recorded interviews, making notes on structured data extraction forms.[222]

Data analysis

Qualitative analysis An analysis schema was developed based on the Question Appraisal System (QAS-99).[231] The QAS-99 is a coding tool that focuses on the cognitive demands required for answering a question, and potentially problematic item characteristics that may lead to response error, such as content, layout/length, time frame and response options, were identified across interviews. Problems from the patient interviews included misunderstanding of the item stem, response options or instructions; unclear wording (i.e. patients used expressions such as 'should', 'needs to', 'must'); and negative comments about an item (e.g. 'that item upset me', 'that item is annoying, it's like the previous one'). The focus of the analysis was on identifying dominant trends across interviews (i.e. problems that occurred repeatedly) and key findings (i.e. problems identified in a single interview, but indicating a potentially problematic issue).[222]

Rasch measurement theory Rasch measurement theory provides a formal method for evaluating scale functioning against a sophisticated mathematical measurement model.[230] The Rasch model defines how a set of items should perform to generate reliable and valid measurements[232] and evaluates the legitimacy of summing items to generate measurements.[230,233] In a Rasch analysis, the extent to which observed data (patients' actual responses to scale items) are concurrent with ('fit') predictions of those responses from the Rasch model is examined, with the difference between expected and observed scores indicating the degree to which rigorous measurement is achieved.[234] The expected response structure is a probabilistic Guttman pattern, which assumes that, for people with the same ability, the probability of endorsing an easy item is higher than the probability of endorsing a more difficult item and vice versa.[235] When a rating scale is used to discriminate between those with different abilities, someone with higher ability is expected to affirm all items endorsed by a person with lower ability in addition to items representative of higher ability. RMT was used to examine the PU-QOL instrument's response options, the appropriateness of the item series and biases arising because of question ordering.

We compared the cognitive interview and Rasch analysis findings in an interactive and iterative process to identify potential strengths and weaknesses of PU-QOL items and to guide decision-making about further revisions to items and the questionnaire design/layout.

Expert appraisal As there is no standard method for using cognitive interview data to modify PRO instruments,[236] the outcome methodologists (see *Acknowledgements*) discussed and resolved aggregated findings (both within and across interviews) after each patient interview round in an iterative process. This was carried out on a consensus, item-by-item basis to decide whether to retain, revise, eliminate or add items or make changes to the design and layout, with particular weight given to the same comments by several patient respondents. Occasionally, a single negative remark led to an item revision (e.g. a remark signalling a serious misunderstanding of an item). A group of clinical experts (see *Acknowledgements*) reviewed the revisions made to ensure clinical relevance. Expert appraisal assisted in avoiding bias that would be introduced when relying solely on the judgement of one researcher in determining the implications of the cognitive interview findings.[222]

Pressure Ulcer Research Service User Network UK appraisal Pressure Ulcer Research Service User Network UK members with experience of living with a pressure ulcer were invited to review the final pre-test version of the PU-QOL instrument and feed back on clarity and comprehension, design and layout and item wording. Responses from PURSUN UK members was fed back to the clinical expert group and incorporated into the final pre-test version.

Ethical approval

The pre-test study was approved by the North West Research Ethics Committee prior to data collection (reference number 08/H1010/112).

Results

We screened 134 patients from 11 acute and community NHS sites across England from April 2009 to September 2009 in three rounds of cognitive interviews. Of those screened, 66 were considered eligible and 35 were recruited to the three rounds (10, 10 and 15 respectively). Patients ranged in age from 36 to 85 years (mean age 65 years) with half (49%) aged ≥ 70 years. In total, 16 (46%) were men and 18 (51%) had an additional chronic condition (e.g. spinal cord injury). Patients represented different settings ($n = 19$ hospital; $n = 4$ rehabilitation; $n = 12$ community) and ulcer severity ($n = 13$ superficial; $n = 18$ severe; $n = 4$ mixed severity), duration (2 weeks up to 5 years) and skin site ($n = 33$ sacrum/buttocks; $n = 13$ heel; others: lower back, groin, hips, back of thighs and ankles).[222]

Cognitive interviews identified five key problem areas: content, instruction/layout/length, recall period, response options and administration mode. For example, patients reported that there were too many items about odour – 'How many different words do you need for smell, you could remove a lot of these' – or items used words that were too sensitive (e.g. 'dirty smell') or not commonly understood (e.g. 'foisty'). Revisions focused on using words that patients use (e.g. 'pressure sore' instead of 'pressure ulcer').[222] Participants preferred responding in terms of how bothered they were about a particular problem rather than simply reporting on the frequency. We also found that almost half of the sample ($n = 15$; 43%) needed some assistance with completing the instrument, which led us to change the mode of administration from self-complete to interview administered to ensure suitability across the wide spectrum of pressure ulcer patients. The optimal mode of administration was tested empirically during the first field test (see *Field test 1 and mode of administration substudy*).

The Rasch analysis highlighted problems with the response options (i.e. the 4-point item response options were not supported; disordered thresholds were found in 74 of 90 items, indicating that the proposed scoring function was not working as intended). However, as the Rasch analysis was preliminary, it was considered premature at this stage to make changes to the response options until further empirical evidence could be obtained.[222] Consistent with the qualitative findings, the Rasch analysis identified item redundancy; examination of item locations indicated that some items clustered at similar locations (e.g. the item 'lacking self-esteem' was considered similar to the items 'feeling self-conscious' and 'lacking confidence' by both methods and was subsequently removed).

The results guided changes to layout, administration mode and content (e.g. item selection and deletion to reduce respondent burden, data errors and non-response). Feedback from PURSUN UK members led to some additional clarification of the instructions and revisions to the item wording for two items (removed item 'upset'; merged items 'concerned' and 'worried' into one item).

Preliminary Pressure Ulcer Quality of Life instrument

The final preliminary PU-QOL instrument consisted of 13 scales (87 items): pain (11 items), exudate (eight items), odour (six items), sleep (six items), malaise (three items), mobility (11 items), daily activities (nine items), mood (seven items), anxiety (three items), self-consciousness and appearance (seven items), autonomy (three items), isolation (four items) and participation (nine items). It was intended for interview administration and responses are given in terms of the amount of bother attributed ('During the past week, how much have you been bothered by . . .?') during the past week on a 4-point response scale (0 = not at all to 3 = a lot).

Phase 3: field testing

To enable the PU-QOL instrument to be used with confidence in clinical practice and future research it must be shown to meet psychometric standards for reliable and valid measurement. The third phase of this project involved a full psychometric evaluation of some of the fundamental measurement properties of the final pre-test version of the PU-QOL instrument.[223] It included two field tests and a mode of administration substudy. The first field test was carried out to identify any items with poor psychometric performance for possible elimination (item reduction) and establish the optimal mode of administration for the instrument (i.e. patient self-completion or researcher administered). The second field test involved a full psychometric evaluation (e.g. tests for scale targeting, item response categories, scaling assumptions, acceptability, reliability and validity) of the item-reduced version of the instrument (see *Appendix 44* for the study protocol).

Field test 1 and mode of administration substudy

The first field test was required to establish the feasibility and acceptability of the PU-QOL instrument, produce a shorter version if appropriate (i.e. reduce the instrument length without losing measurement precision) and identify subscales and test scaling assumptions.

Aims

This study aimed to:

1. confirm the feasibility and acceptability of the instrument
2. produce a scientifically robust shorter version by selecting items that perform best against established psychometric criteria
3. examine the legitimacy of summing items into scales and test scaling assumptions
4. carry out a preliminary evaluation of the reliability and validity of the shorter item-reduced version
5. empirically investigate the optimal mode of administration (i.e. establish whether the PU-QOL instrument can be developed for use with both self-completion and interview-administered modes or whether two mode-specific instruments are required).

Methods

Design

A field test was carried out to evaluate the PU-QOL instrument's response format, scales and items in an independent sample of patients with pressure ulcers. Part of the field test included a mode of administration substudy to provide empirical support for the chosen mode of administration (i.e. interview administered) for the PU-QOL instrument. Initially, the intention was for the PU-QOL instrument to be self-completed; however, pre-testing identified problems with completion rates (see *Pre-testing*, *Results*), questioning the appropriateness of a self-completed instrument for patients with pressure ulcers.

Participants

Eligibility Patients from selected acute and community NHS trusts in England and Scotland were included in the field test and substudy if they were aged ≥ 18 years and were hospital, intermediate care including rehabilitation, nursing home or community patients with an existing pressure ulcer of any category, location or duration and were able to provide informed consent to participate.[223] Patients were excluded if they had only moisture lesions or were unconscious, confused or cognitively impaired, it was deemed ethically inappropriate to approach them (e.g. death was imminent), they did not speak or understand English or they were unable to provide informed consent. To ensure equivalent samples in both administration mode groups, the eligibility criteria were adapted for the substudy to include only patients able to read and write in English (i.e. patients able to self-complete).

Sampling Between 200 and 250 patients with pressure ulcers were purposively sampled ensuring balanced representation of patients across ulcer categories (superficial and severe) and location (torso and limb skin sites), settings (acute and community), age (< 70 years and ≥ 70 years) and gender.[223] No formal sample size estimation methods for the evaluation of PRO instruments were found. The 'rule of thumb' sample size recommendation for psychometric analyses of new summated scales is five to 10 subjects per item, to reduce the effect of chance.[194,195] Following this recommendation, if we take the longest potential summated scale, assessing pain, which contains 11 items, a 110-patient sample would be required. For the Rasch analysis, a sample of 200–250 patients was sought. This estimate was based on a need for sample selection across the full range of measurement. Sample membership to five class interval groups [i.e. different levels (class intervals) of a person factor, e.g. ulcer severity] of around 50 patients in each group is suggested.[233,237]

A subsample (60–100 patients) was recruited to the mode of administration substudy. It was anticipated that up to 100 patients would be required to meet the data requirement for the differential item functioning (DIF) analysis and to account for the likelihood of missing data from the self-complete group. RMT methods are able to provide useful exploratory data in small samples ($n > 30$).[238]

Recruitment and data collection

Consecutive patients were identified and approached to participate in the study by attending clinical teams at participating trusts. Screened patients who were eligible were provided with a study information leaflet and consent form (see *Appendix 47*). Patients who provided informed consent but who were unable to self-complete the PU-QOL instrument were registered into the field test study. Those who were eligible and able to self-complete the PU-QOL instrument were registered and enrolled into the substudy.

The PU-QOL instrument was administered to all patients by tissue viability team members or the researcher, following the PU-QOL user manual. The user manual was developed to provide information about how to administer the PU-QOL questionnaire and encourage standardisation across administration. It outlines the administration procedure, includes some helpful question and answers and provides scoring information. Patients enrolled to the substudy and randomised to the self-completion group were provided with the PU-QOL instrument and instructed to complete it on their own. Completion took approximately 16 minutes.

Substudy randomisation

Substudy registrants were randomised by telephone on a 2 : 1 basis to either the self-completion or the interview-administered mode of administration. The 2 : 1 ratio was used to account for the likelihood of there be being more missing data from self-completed questionnaires. Randomisation was stratified by age (< 70 and ≥ 70 years) and ulcer severity (superficial vs. severe).

Analytical methods

Conventionally, PRO instruments or rating scales have been developed and evaluated according to traditional psychometric standards derived from CTT.[195,239] CTT comprises a set of principles and related statistical techniques for developing and testing measures (e.g. PRO instruments) to determine how successful they are at estimating unobservable (e.g. HRQoL) variables of interest.[240] However, some concerns have been raised about existing PRO instruments developed according to CTT: they may be cumbersome for respondents, be burdensome for clinical use, not be applicable over the continuum of care or across research settings, suffer from floor and ceiling effects and/or lack a standardised scoring metric to allow comparisons across health conditions.[241–244]

More recent advances in psychometrics have seen the development and application of modern psychometric methods such as RMT to supplement traditional approaches to rating scale development.[244] Both RMT and traditional psychometric methods were used to psychometrically evaluate the PU-QOL instrument. Using both methods would allow the selection of scale items that are free of bias, confirm the legitimacy of summing scale items to generate measurements (Rasch) and determine whether or not the measurements produced are valid and reliable in line with proposed US FDA criteria for reliability and validity.[212] *Table 72* presents full details of the tests and criteria used in the psychometric evaluation.

TABLE 72 Psychometric tests and criteria

Property	Definition of psychometric property	Criteria Rasch methods	Criteria traditional methods
Data quality – acceptability/data completeness	The extent to which scale items are scored and total scores can be computed. Acceptability determined by data quality; assessed by completeness of item- and scale-level data (percentage of missing data for each item; percentage of people for whom a scale score is computed[245]) and score distributions (floor/ceiling effects and skew of scale scores)	• Even distribution of endorsement frequencies across response categories (> 80%) • Low number of people at extreme (i.e. floor/ceiling) ends of the measurement continuum	• Item-level missing data < 10%[246] • Computable scale scores > 50% completed items[247] • Items in scales rated 'not relevant' < 35%
Scaling assumptions	The extent to which it is legitimate to sum a set of items, without weighting or standardisation, to produce a total score. Summing item scores is considered legitimate when items: • are approximately parallel [i.e. they measure at the same point on the scale (redundancy)] • contribute similarly to the variation in the total score (i.e. similar variances), otherwise items should be standardised • measure a common underlying construct • contain a similar proportion of information concerning the construct being measured, otherwise items should be given different weights[248]	• Positive residual correlation between items (> 0.30) suggests local dependency • High negative residual correlation (> 0.60) suggests redundancy • Items sharing common variance suggests unidimensionality • Evenly spaced items spanning the whole measurement range of the continuum	• Similar item mean scores[248] and SDs[245] • Items have adequate corrected ITC (≥ 0.3)[247] • Items have similar ITCs[247]
Item response categories	The extent to which item response categories work in a logical hierarchy reflecting the measurement continuum within the frame of reference of the scale. Respondents with high levels of the trait measured by the scale are expected to endorse high-scoring responses, whereas individuals with low levels would consistently endorse low-scoring responses. Disordered thresholds occur if respondents fail to use the response options in a manner consistent with the level of the trait being measured[249]	• Ordered set of response thresholds for each scale item	• NA

Property	Definition of psychometric property	Criteria Rasch methods	Criteria traditional methods
Targeting	The extent to which the range of the variable measured by the scale matches the range of that variable in the study sample. This involves examination of score distributions at both the item and the scale level within the whole sample and also by disease severity subgroups. Evidence of matched scale-to-sample targeting focused around the scale's best point of measurement. A well-targeted sample is one in which the person distribution closely matches the item distribution (person locations should be covered by items and item locations should be covered by persons) when they are both calibrated on the same metric scale[250]	• Person-item threshold distribution: the extent to which the range of the variable (scale item locations) matches the range of that variable in the study sample (person locations) – good targeting demonstrated by the mean location of items and persons around zero • Items should span the full range of person estimates	• Scale scores spanning the entire scale range • Floor (proportion of the sample at the minimum scale score) and ceiling (proportion of the sample at the maximum scale score) effects should be low (< 15%)[251] • Skewness statistics should range from –1 to + 1[252] • No published criteria for item-level targeting; scale-level criteria used
Reliability	The ability of a measure to yield the same score at each administration, assuming that all things are equal (i.e. true change has not occurred) and the extent to which scale scores are free from random error		
Internal consistency	The extent to which items comprising a scale measure the same construct (e.g. homogeneity of the scale)	• High person separation index (> 0.7);[253] quantifies how reliably person measurements are separated by items • Power of tests indicates the power to detect the extent to which the data do not fit the model (fit statistics are interpreted in light of the power)[237] • Items with ordered thresholds	• Cronbach's alphas for summary scores (adequate scale internal consistency is ≥ 0.70[195]) • ITC between + 0.4 and + 0.6 indicates that items are moderately correlated with scale scores; higher values indicate items that are well-correlated with scale scores[195]
Test–retest reliability[a]	The stability of a measuring instrument; assessed by administering the instrument to respondents on two different occasions and examining the correlation between the test and the retest scores. This indicates the strength of the relationship between scores at baseline and time 2 (retest 2–7 days post baseline administration)	• Statistical stability across time points [no uniform or non-uniform DIF ($p \geq 0.05$ or Bonferroni adjusted value)]	• Scale-level ICCs > 0.70[254] between test and retest scores • Pearson correlation – high correlations (> 0.7) indicate reliable scale stability

continued

TABLE 72 Psychometric tests and criteria (*continued*)

Property	Definition of psychometric property	Criteria Rasch methods	Criteria traditional methods
Validity	The extent to which a scale measures what it intends to measure; a scale may be reliable but consistently measure the wrong thing[255] (e.g. demonstrating that a set of items intended to measure pain has good reliability merely indicates that the items are getting the same true score but not necessarily tapping into the true pain score[240])		• Evaluating validity involves accumulating evidence from different forms
Content validity	The extent to which the content (items) of a scale is representative of the conceptual construct that it is intended to measure. Consideration of item sufficiency and the target population is essential, including systematic comparison with existing standards, well-accepted theoretical definitions, expert opinions and interviews with individuals at whom the measure is targeted[212]	• Clearly defined construct • Validity comes from careful item construction and consideration of what each item is meant to measure, then testing against model expectations	• Qualitative evidence from patients, expert opinion and literature review that items in the scale are representative of the construct being measured
Construct validity	Indicates the degree to which a measure represents what it is intended to represent		
Within-scale analysis	Evidence that a single entity (distinct construct) is being measured and that items can be combined to form a scale score. *Item fit statistics* imply that an item is not working as intended in a scale and may be regarded as not measuring the scale's intended construct. Three-item fit statistics indicate the extent to which observed data (actual responses to scale items) accord with (fit) responses expected for groups of responders across the trait (class intervals): fit residuals, chi-square statistics and item characteristic curves.[256] For meaningful interpretation, findings are considered together and in the context of their clinical usefulness as an item set	• Fit residuals (item–person interaction) within given range ±2.5 • Non-significant chi-square (item–trait interaction) values • No under- or overdiscriminating ICCs (graphical indicator of model fit/misfit) • Mean fit residual close to 0.0, SD approaching 1.0 (usually < 1.4) for summary statistics[257] • Person fit residuals within given range ± 2.5	• Cronbach's alpha for scale scores > 0.70 ITC > 0.30 • Homogeneity coefficient (inter-item correlation mean and range > 0.3) • Scaling success

Property	Definition of psychometric property	Criteria Rasch methods	Criteria traditional methods
	RMT purports that the aim of scale items is to mark out the construct as a continuum on which people can be measured. Measurement continuum implies that individual scale items are located across a continuum in the same way that the location of individual people is spread across the continuum[241]	• Items spread evenly over a reasonable measurement range[256,258] and are appropriately targeted to people who they are measuring. Items with similar locations may indicate that an item is redundant	• NA
	A problem with the local dependence of items can be found by response dependency. The assumption of local independence implies that once the Rasch factors have been extracted (final scales) no leftover patterns in the residuals should be present. Response dependency is when items are linked in some way such that the response to one item will determine the response to another	• Local independence is indicated by an absence of any meaningful pattern in the residuals[259] • Response dependency is indicated by residual correlations > 0.3 for pairs of items[256,258]	• NA
Between-scale analysis			
Criterion validity	A special type of construct validity in which stronger hypotheses are made possible by the availability of a criterion or 'gold standard' measure	• NA	• There are no true gold standard HRQL,[229] PU-specific or chronic wound-specific measures available[216]
Convergent validity[a]	Evidence that the scale is correlated with other measures of the same or similar constructs; assessed on the basis of correlations. Correlations are expected to vary according to the degree of similarity between the constructs measured by each instrument. Specific hypotheses are formulated based on the proximity of constructs and predictions tested on the basis of correlations	• NA	• Moderate to high correlations predicted for similar scales; criteria used as guide to the magnitude of correlations, as opposed to pass/fail benchmarks (high correlation $r > 0.7$; moderate correlation $r = 0.3$–0.7; low correlation $r < 0.3$).[198,199] Moderate to high correlations ($r \geq 0.3$) were predicted between PU-QOL and SF-12 scales
Discriminant validity[a]	Evidence that the scale is not correlated with measures of different constructs; assessed on the basis of correlations with measures of different constructs (e.g. age, gender) to determine whether responses are biased by these variables	• NA	• Low correlations (< 0.3) predicted between scale scores and measures of different constructs. Low correlations were predicted for gender and age

continued

TABLE 72 Psychometric tests and criteria (*continued*)

Property	Definition of psychometric property	Criteria Rasch methods	Criteria traditional methods
Known-groups differences[a]	The ability of a scale to differentiate known groups; assessed by comparing scores for subgroups known to differ on the construct being measured (significant differences between known groups or difference of expected magnitude). Note: The PU HRQL literature is not well established and therefore was limited for identifying clinical parameters to formulate known groups	• Hypothesis testing (e.g. clinical questions are formulated and the empirical testing comes from whether or not data fit the Rasch model)	• Generate hypotheses and compare mean scores (i.e. predict a stepwise change in PU-QOL scale scores across three PU severity groups and that mean scores would be significantly different) • ANOVA to indicate statistically significant differences in mean scores between PU severity subgroups and PU-QOL exudate and odour scales. For the remainder of the scales, known-groups difference validity was investigated on an exploratory basis, predicting a stepwise change in PU-QOL scores across PU severity groups
DIF (item bias)	A technique for investigating conditional relationships between item response and group membership.[260] It is based on the assumption that respondents with a similar knowledge or ability (determined by total scale scores) should perform or respond in similar ways to individual items regardless of characteristics such as gender, age or ethnicity, Groups to be studied are selected based on theoretical considerations about whether or not the construct studied is hypothesised to have the same conceptual meaning across groups. DIF occurs when people from different groups (e.g. gender) with the same latent trait (e.g. pain) have a different probability of giving a certain response to an item	• Respondents with a similar ability should respond in similar ways to individual items regardless of group membership • Uniform DIF – item shows the same amount of DIF regardless of person ability (uniformity amongst differences between groups) • Non-uniform DIF – DIF varies according to ability (non-uniformity amongst differences between groups) • DIF can be considered at both 1% (Bonferroni adjusted) and 5% CIs	• NA
Responsiveness	The ability of a scale to detect clinically significant change following treatment of known efficacy; assessed by within-person change scores from before to after treatment and by calculating an effect size statistic (mean change score divided by the SD of the pre-treatment score)	• Racking and stacking data for analysis (stablility of scale over time) and DIF (item stability over time)[250]	• Moderate to large effect sizes (small 0.20, moderate 0.50, large $\geq$0.80)[261]

ANOVA, analysis of variance; ICC, intraclass correlation; ITC, item–total correlation; NA, no equivalent test; PU, pressure ulcer; *r*, correlation.
a Additional tests performed for field test 2 (evaluation of the final PU-QOL instrument).
Source: Table adapted from the US Department of Health and Human Services FDA,[212] Gorecki *et al.*,[223] Hobart and Cano,[250] Cano *et al.*[262] and Lamping *et al.*[263]

Rasch measurement psychometric analysis First, RMT methods[230] were used to investigate the PU-QOL instrument items within the context of the instrument, response options, appropriateness of item series (i.e. item content, response bias, dimensionality, precision) and question ordering (item fit) to evaluate how well items, scales and response options work to measure what they are intended to measure.

A Rasch analysis, using the Andrich rating scale model,[264] was performed using RUMM2030 software (RUMM Laboratory, Perth, WA, Australia), comprising targeting of the sample to items, ordering of response options (i.e. ordering of item thresholds)[249] and item-fit statistical indicators (i.e. fit residual and chi square[256] and spread of item locations;[256,258] see *Table 72*). PU-QOL data were tested against model expectations and any deviations from model expectations were examined to determine whether or not scale attributes could be improved. Final decisions on item inclusion/exclusion were made according to appraisals of the analyses of the observed data against measurement criteria described in *Table 72*, and clinical relevance (the extent to which items within proposed scales are clinically cohesive), as opposed to examinations carried out singularly or sequentially.

Substudy analysis Response rate, data quality and DIF analyses[265] were undertaken to establish measurement equivalence across the two mode of administration groups (self-completion and interview administered). DIF provides a method of exploring conditional relationships between item response and group membership by examining the significance of differences observed between different levels (class intervals) of a person factor (e.g. administration mode group).[260] Groups to be studied are selected based on theoretical considerations about whether or not the construct studied is hypothesised to have the same conceptual meaning across groups.

Traditional psychometric analysis: preliminary psychometric evaluation To determine whether or not the PU-QOL instrument fulfilled fundamental prerequisites for rigorous measurement as defined by traditional psychometric criteria and the US FDA guidance,[212] the Rasch model-developed PU-QOL scales underwent a preliminary psychometric evaluation using standard psychometric tests.[212,225,250,254,263,266] The scales were examined for acceptability and data quality, scaling assumptions, targeting, reliability and construct validity against prespecified criteria (see *Table 72*). As RMT provides a formal method of testing the degree to which rigorous measurement is achieved by PRO scales, use of factor analysis to determine scale structure was not deemed necessary. The psychometric tests were performed using SPSS 15.0 software (SPSS Inc., Chicago, IL, USA).

Ethical approval

The two field tests were approved by the North West Research Ethics Committee prior to data collection (reference number 08/H1010/112).

Results

Sample

A total of 989 patients were screened for participation in the first field test from 21 hospitals, 10 community services and one hospice. Of those screened, eligibility was assessed for 787 (79.6%); 416 were considered eligible (52.9%) and, of those eligible, 285 (68.5%) consented to participate (*Figure 29*). Cognitive impairment was the main reason for ineligibility (38.8%). Those able to self-complete were included in the substudy ($n = 75$), with 54 randomised to the self-completion group and 21 randomised to the researcher-administered group; the remaining 210 participants were registered to the main study. The main study analysis population included those able to self-complete and randomised to the researcher-administered group in the substudy ($n = 21$) plus those registered to the main researcher-administered study ($n = 206$). The final analysis populations after exclusions included 70 participants in the substudy and 227 in the main study (see *Figure 29*). *Table 73* presents the characteristics of the final analysis samples.

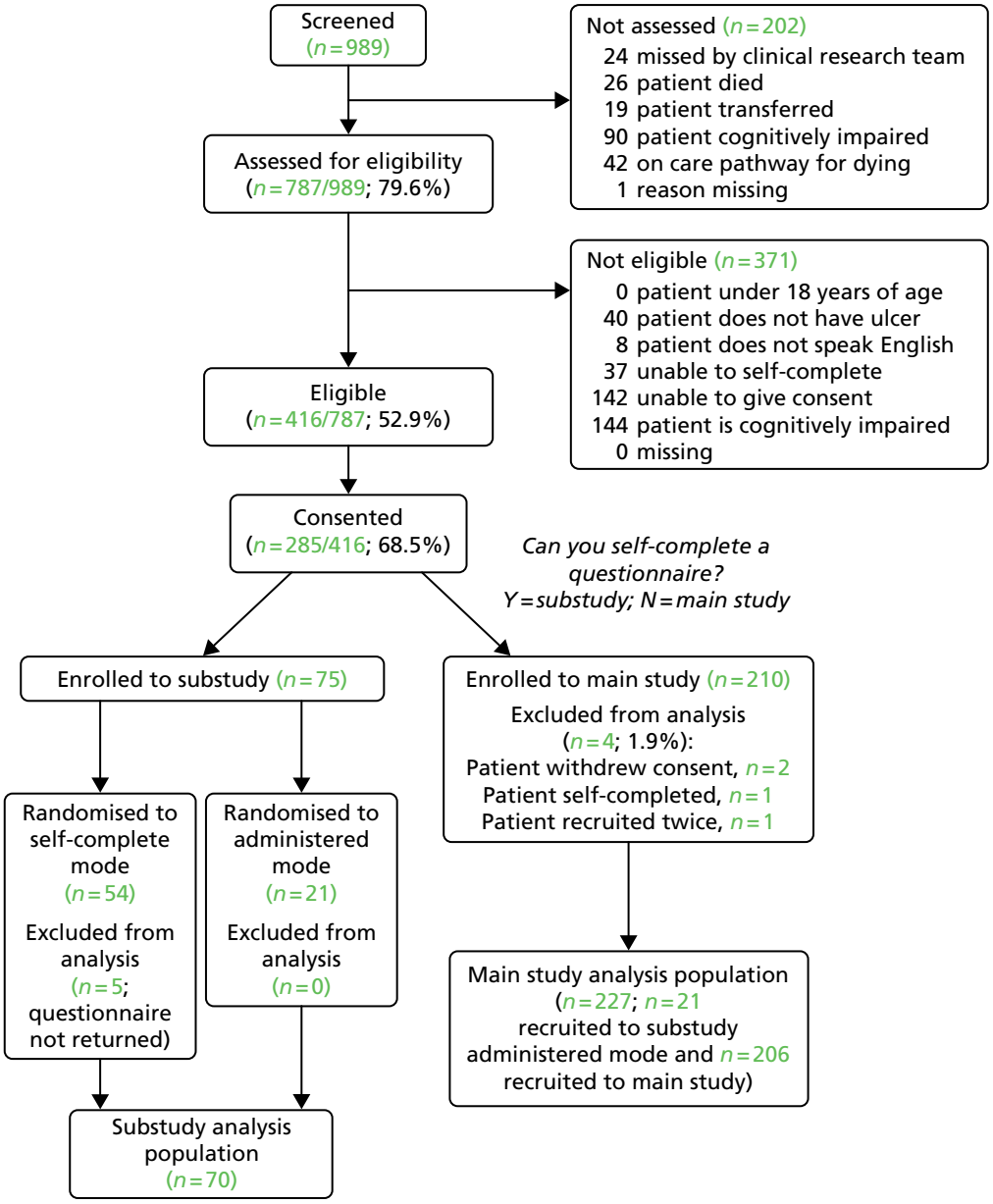

FIGURE 29 Assessment flow chart for the substudy and field test 1.

TABLE 73 Participant characteristics in the substudy and field tests 1 and 2

Characteristic	Substudy ($n = 70$)	Field test 1 ($n = 227$)	Field test 2 ($n = 229$)
Age (years), range (mean, SD)	21–93 (64, 15)	24–98 (72, 13.5)	20–103 (71.3, 16.5)
Gender, *n* (%)			
Male	47 (67.1)	90 (39.6)	119 (52.0)
Female	23 (32.9)	137 (60.4)	110 (48.0)
Ethnicity, *n* (%)			
White	NA	223 (98.2)	227 (99.1)
Asian	NA	1 (0.4)	2 (0.9)
Black/African	NA	2 (0.9)	0
Chinese	NA	0	0
Not stated	NA	1 (0.4)	0
Setting, *n* (%)			
Hospital (surgery)	38 (54.3)[a]	99 (43.6)	62 (27.1)
Hospital (medicine)		21 (9.3)	74 (32.3)
Community	32 (45.7)	107 (47.1)	88 (38.4)
Missing	0	0	5 (2.2)
Pressure ulcer severity, *n* (%)			
Category 1	40 (57.1)[b]	38 (11.3)	76 (18.1)
Category 2		144 (42.9)	170 (40.5)
Category 3/4	30 (42.9)	153 (42.7)	170 (40.5)
Missing	0	1 (0.3)	4 (0.9)
Pressure ulcer risk classification, *n* (%)			
Short term	NA	39 (17.2)	36 (15.7)
New medium to long term	NA	71 (31.3)	87 (38.0)
Ongoing long term	NA	116 (51.1)	103 (45.0)
Missing	NA	1 (0.4)	3 (1.3)
Marital status, *n* (%)			
Single (includes divorced, separated, widowed)	NA	59 (26.0)	71 (31.0)
Married	NA	85 (37.4)	77 (33.6)
Cohabiting	NA	81 (35.7)	75 (32.8)
Missing	NA	2 (0.9)	6 (2.6)
Living arrangements, *n* (%)			
Live alone	NA	84 (37.0)	86 (37.6)
Cohabit with carer	NA	63 (27.8)	51 (22.3)
Cohabit with other	NA	61 (26.9)	48 (21.0)
Missing	NA	19 (8.4)	44 (19.2)
Education, *n* (%)			
No formal education	NA	129 (56.8)	125 (54.6)
GCSE or equivalent	NA	39 (17.2)	40 (17.5)
A-Level or equivalent	NA	25 (11.0)	16 (7.0)
Degree or higher	NA	15 (6.6)	21 (9.2)
Missing	NA	19 (8.4)	27 (11.8)

A-level, Advanced Level; GSCE, General Certification of Secondary Education; NA, information not available.
a Combined hospital sample.
b Combined category 1 and 2 sample.

Mode of administration substudy

The substudy provided qualitative and empirical evidence for the selection of the most appropriate administration mode for people with pressure ulcers. Qualitative findings highlighted difficulties with patient self-completion. PU-QOL forms returned with missed items were examined to investigate patterns in missing responses and the following observations were noted. Of the 19 self-completed PU-QOLs with missing data, four respondents wrote 'n/a' next to items missed; six completed only one item per scale; five missed items at random; two missed a page; one missed items from only the daily activities scale; and one mostly missed items at the beginning. Of the three researcher-administered PU-QOLs with missing data, one had one item missed and one had two items missed; in the other case the patient asked to stop completing the PU-QOL because of feeling ill, resulting in a large amount of items ($n = 26$) missed towards the end. No obvious patterns in responses emerged. We concluded that, if length was an issue for missing data, we would expect to see more missing data towards the end of the questionnaire (i.e. when patients became tired or fed up with completing a long questionnaire). However, this pattern was not observed. Rather, patients were not responding to items as instructed, resulting in missing data.

Investigation of response rate and data quality indicated a difference in response rate between administration methods: 90.7% of the self-completed PU-QOL forms compared with 100% of the administered PU-QOL forms were returned, an overall high response rate. A difference was also observed in data quality: a large proportion of PU-QOL forms were returned with missing data in the self-completed group (*Table 74*), supporting the pre-test findings (see *Pre-testing*, *Results*). Inspecting returned PU-QOL forms by setting, missing data were observed mostly on forms that were self-completed by patients in hospital (see *Table 74*), although preliminary DIF analysis indicated that administration mode did not impact on the way that community patients responded to PU-QOL items, supporting the equivalence of

TABLE 74 Data quality: missing data (substudy population)

Characteristic	Self-completed ($n = 49$)	Administered ($n = 21$)	Total[a] ($n = 70$)
PU-QOL forms with missing data, *n* (%)	19 (38.8)	3 (14.3)	22 (31.4)
Total number of PU-QOL items missed (range 1–87 items per PU-QOL), *n* (%)	619 (14.5)	29 (1.6)	648 (10.6)
Age			
< 70 years			
Number with missing data	12/25	2/14	14/39
Number (%) of items missed	336 (15.5)	3 (0.3)	345 (10.2)
≥ 70 years			
Number with missing data	7/24	1/7	8/31
Number (%) of items missed	283 (13.6)	26 (4.3)	309 (11.5)
Health-care setting			
Acute			
Number with missing data	16/26	2/12	18/38
Number (%) of items missed	604 (26.7)	28 (2.7)	632 (19.1)
Community			
Number with missing data	3/23	1/9	4/32
Number (%) of items missed	15 (0.8)	1 (0.1)	16 (0.6)

a A total of 75 patients were randomised and 70 PU-QOL forms were returned and analysed (five completed forms were lost in the post).

self-completed and interview-administered versions in community populations. The DIF analysis was an important methodological step for highlighting areas warranting further investigation if pursuing a self-completed version in the future. Based on the substudy findings we continued evaluating only a researcher-administered version.

Item reduction and scale formation: Rasch analysis

The Rasch analysis detected important limitations of the PU-QOL scales, resulting in minor modifications.[223] It detected that the four-category item scoring function did not work as intended for one or more items within one or more scales, as demonstrated by disordered thresholds. For the other items, for which the response categories were working as intended, thresholds were close to being disordered, suggesting that people had difficulty distinguishing between the categories 'a little bother' and 'quite a bit of bother'. This provided good evidence that items would benefit from having fewer response categories. Consequently, all scale items were subjected to a post hoc rescoring by collapsing adjacent categories (so that all items had three response categories). Reanalysis of the data demonstrated that all thresholds were now correctly ordered, producing scales with new categories (0 = no bother, 1 = little bother, 2 = a lot of bother).

Another important finding was suboptimal scale-to-sample targeting.[223] There were significant floor effects; the largest frequency of patients was often at the floor of the scale ranges ('least bother'), suggesting that the scales might provide limited information about people at the extremes of the sample distribution (those with the least disability or impairment). Ideally, there should be a good match between the scale range and the sample range, with people falling within the range of the items. However, the ordering of scale items along each variable was clinically sensible, providing evidence of the construct validity of each scale variable.

Three items had notable criterion failures as defined by a fit residual level outside ±2.5, high chi-square values with significant *p*-values and adherence to the item characteristic curve (significantly underdiscriminating or overdiscriminating). Few items exceeded residual correlations of +0.3, implying that the responses to items are independent of each other and locally independent, or –0.3, suggesting no redundant items. Departures from item fit expectation were relatively small but when considered in combination resulted in six items being removed (see *Appendix 43*). Person separation index values indicated good to reasonable reliability for scales distinguishing between responders on each scale variable.

At this stage, items that were considered clinically important but which did not fit into existing scales were retained as single items (e.g. itchiness). Scales that did not meet requirements for reliable and valid measurement were either conceptually combined (e.g. items representing mood, anxiety, autonomy and isolation were combined into an emotional well-being scale) or had items added [e.g. three items, determined from patients transcripts (see *Item generation from patients*), were added to the vitality and malaise scale to produce a six-item scale], reducing the instrument from 13 to 10 scales. The final scales and items are presented in *Appendix 43*.

Preliminary psychometric evaluation: traditional analysis

The results of the psychometric evaluation using traditional psychometric tests supported the PU-QOL scales as being reliable and valid measures of pressure ulcer-symptoms, physical and social functioning and psychological well-being.[223] The criteria were satisfied for most psychometric properties evaluated. Briefly, data quality was high (scale scores were computable for 93–99.6% of respondents) and scaling assumptions were satisfied [mostly similar mean item scores; corrected item–total correlation (ITC) ranges 0.525–0.920]. Scale-to-sample targeting was good [scale scores spanned the scale range but were notably skewed for three scales (value outside ±1.0), mean scores were near the scale mid-point for six of nine scales and ceiling effects were negligible; however, floor effects exceeded the 15% criterion for two of nine scales]. Internal consistency reliability was high, as demonstrated by Cronbach's alpha values (range 0.893–0.962). The ITCs, alpha coefficient and homogeneity coefficient (inter-item correlation mean and range) provide evidence of the internal construct validity of the PU-QOL scales. A full psychometric evaluation was planned for field test 2.

Field test 2: final psychometric evaluation

The second field test was used to perform a full psychometric evaluation of the item-reduced version of the PU-QOL in a large independent sample of patients with pressure ulcers[223] (see *Appendix 44* for the study protocol).

Aim

The study aimed to provide researchers and clinicians with a comprehensive evaluation of some of the fundamental psychometric measurement properties of the final (10-scale/83-item) PU-QOL instrument, including scale targeting, item response categories, item fit, response bias, acceptability, scaling assumptions, reliability and validity.

Methods

Design

The second quantitative field test was undertaken to carry out a comprehensive psychometric evaluation of the final PU-QOL instrument, in a large independent sample of patients with pressure ulcers. Consistent with methods used in the first field test (see *Field test 1 and mode of administration substudy*, *Design*), a Rasch analysis was performed first on all PU-QOL scales, followed by traditional psychometric tests (see *Table 72*), in line with current US FDA guidance.[212]

Participants

Eligibility The eligibility criteria for the second field test were consistent with those used in the first field test (see *Field test 1 and mode of administration substudy*, *Eligibility*).

Sampling A total of 200–250 patients with pressure ulcers was purposively sampled, consistent with methods described in *Field test 1 and mode of administration substudy* (see *Sampling*). This provided sufficient subjects for test–retest analysis; correlations at levels expected in test–retest situations ($r \geq 0.80$) can be estimated with reasonable precision (95% CIs of ± 0.1) with relatively few subjects.[267,268]

Recruitment and data collection

The recruitment method for the second field test was consistent with that detailed in *Field test 1 and mode of administration substudy* (see *Recruitment and data collection*; see also *Appendix 48* for the patient information leaflet and consent forms).

A questionnaire pack containing the PU-QOL and the SF-12 was administered to all participants. The SF-12v2 Acute, English (UK) version was used[269] to minimise respondent burden. This is a generic measure that asks respondents to rate their health and functioning during the past week on eight domains: physical functioning, role physical, bodily pain, general health, energy/fatigue, social functioning, role emotional and mental health.

A subsample of 50–60 patients completed a second PU-QOL 2–7 days after the first to evaluate test–retest reliability. The test–retest interval had to be short enough to ensure that clinical change in the pressure ulcer was unlikely to occur but sufficiently long so that respondents did not recall their responses from the first administration; a short test–retest interval is necessary to evaluate stability per se, rather than clinical change in the pressure ulcer. The tissue viability team member returned to administer the second PU-QOL to all patients who agreed to the second administration, either on the ward or at their home, within the specified time frame.

Analytical methods

Consistent with methods used in the first field test (see *Field test 1 and mode of administration substudy*, *Analytical methods*), both RMT and traditional psychometric methods were used to psychometrically evaluate the final PU-QOL instrument. *Table 72* presents full details of the tests and criteria used in the psychometric evaluation.

Rasch measurement psychometric analysis The Rasch analysis was consistent with methods used during the first field test (see *Field test 1 and mode of administration substudy*, *Analytical methods*, and *Table 72*). Additional tests for person fit and uniform and non-uniform DIF in relation to four clinical subgroupings [age (< 70 years and ≥ 70 years), gender (male and female), ulcer location (torso, limb, both) and health-care setting (hospital and community)] were considered during the final psychometric evaluation (see *Table 72*).

Traditional psychometric analysis The final Rasch scales underwent a psychometric evaluation using the same traditional psychometric tests examined during field test 1 (see *Field test 1 and mode of administration substudy*, *Analytical methods*) plus additional tests for reliability (test–retest) and validity (convergent and discriminant validity and known-groups differences) (see *Table 72*).

Missing data were not imputed. The frequency of missing data was determined and items with a response rate of < 90% were investigated.

Results

Sample

In total, 879 patients were screened for study participation, of whom eligibility was assessed for 717; of these, 391 were considered to be eligible of whom 231 consented to participate. The final analysis population was 229 after exclusions (*Figure 30*). *Table 73* presents the characteristics of the analysis sample.

Rasch analysis

The measurement properties of the PU-QOL scales were largely supported as demonstrated by items that mapped out continua of increasing intensity and are located along those continua in a clinically sensible order. Scale items work well together to define single variables, albeit some item misfit, local dependence and items exhibiting DIF were detected. For example, DIF was demonstrated in three items (*Table 75*); however, the deviations from model expectations were marginal, suggesting that item performance across the four clinical subgroups is stable and that these groups can be measured on a common ruler.

The Rasch analysis detected important limitations of some PU-QOL scales. It detected that the three-category item scoring function did not work as intended for 16 out of 82 scale items (see *Table 75*). Some item locations indicated areas on the continuum within the scale range measured where the measurement could be improved (i.e. at extreme ends of the scale range). As the sample sizes for these scales were quite small, major modifications to items and the scoring function were deemed premature without additional empirical evidence.

Another limitation pertains to the sample distribution. For most scales the sample was not normally distributed (normal distribution is neither expected nor wanted as sample distribution is an empirical finding rather than a requirement, but it does suggest that assumptions about the distribution of people and the variables measured in populations should not be made).[250] The largest frequency of patients was often at the floor of the scale ranges ('least bother'), suggesting suboptimal targeting of the PU-QOL scales to the study sample. Ideally, there should be a good match between the scale range and the sample range, with people falling within the range of the items (see *Table 75*). For the symptom scales, the targeting can be justified as not all patients with pressure ulcers are expected to have problems with symptoms and so it is clinically reasonable that these people would fall outside the scale range. Importantly, when people have symptom bother, there need to be items within the scales that will discriminate symptom bother and, in this instance, the symptom scales perform this function.

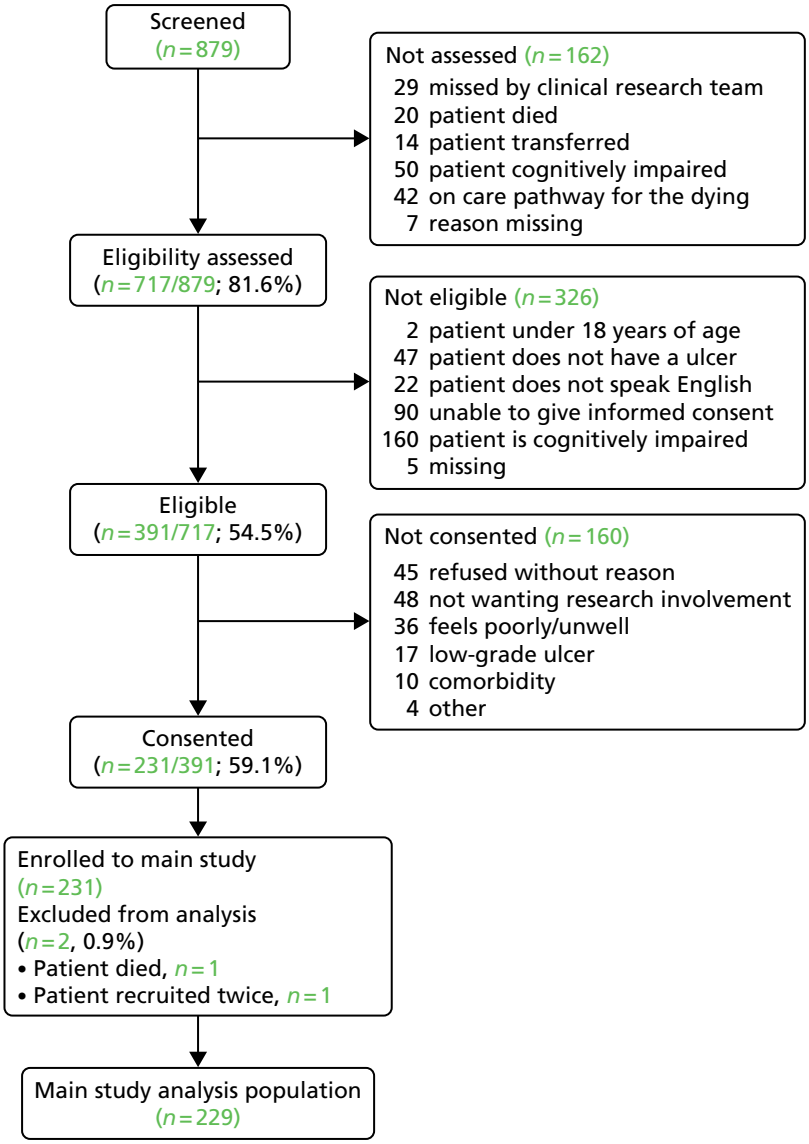

FIGURE 30 Assessment flow chart for field test 2.

TABLE 75 Field test 2: Rasch analysis summary statistics for PU-QOL scale items

Scale items	Threshold	Location	FR	CS	*p*-value	Person–item correlations	DIF age		DIF gender		DIF setting	
							Uniform	Non-uniform	Uniform	Non-uniform	Uniform	Non-uniform
Pain scale* (n = *180; 4 Class interval; PSI = 0.814)												
Uncomfortable	Ordered	–1.104	–0.771	6.527	0.089	< 0.3	+	+	+	+	+	+
Tenderness	Ordered	–1.069	–0.192	3.708	0.295	< 0.3	+	+	+	+	+	+
Annoying	Ordered	–0.670	–1.817	7.508	0.057	< 0.3	+	+	+	+	+	+
Red raw	Ordered	0.219	–0.145	2.065	0.559	< 0.3	+	+	+	+	+	+
Stinging	Ordered	0.388	–0.496	2.817	0.421	< 0.3	+	+	+	+	+	+
Burning	Ordered	0.482	0.328	0.314	0.957	< 0.3	+	+	+	+	+	+
Throbbing	Ordered	0.729	0.692	4.205	0.240	< 0.3	+	+	+	+	+	+
Stabbing	Ordered	1.024	0.519	6.468	0.091	< 0.3	+	+	+	+	+	+
Exudate scale* (n = *59; 2 Class interval – people with only superficial PUs removed, if retained* n = *95; PSI = 0.598)												
Dressing off	Disordered	–0.751	0.804	0.020	0.887	< 0.3	+	+	+	+	+	+
Staining	Ordered	–0.398	–0.758	0.367	0.544	< 0.3	+	+	+	+	+	+
Weeping	Ordered	–0.356	–0.342	0.670	0.413	< 0.3	+	+	+	+	+	+
Sticky	Ordered	–0.266	–0.129	0492	0.483	< 0.3	+	+	+	+	+	+
Messy	Ordered	–0.006	–1.264	4.607	0.032	< 0.3	+	+	+	+	+	+
Running	Ordered	0.252	–0.269	0.255	0.613	< 0.3	+	+	+	+	+	+
Bleeding	Ordered	0.683	0.552	1.493	0.222	< 0.3	+	+	+	+	+	+
Pus	Ordered	0.843	1.566	2.599	0.107	< 0.3	+	+	+	+	+	+
Odour scale* (n = *21; 2 Class interval – people with only superficial PUs removed, if retained* n = *27; PSI = 0.486)												
Unpleasant	Ordered	–1.303	–0.039	1.340	0.247	< 0.3	+	+	+	+	+	+
Lingering	Ordered	–0.207	–0.915	2.186	0.139	< 0.3	+	+	+	+	+	+
Pungent	Ordered	–0.187	0.330	1.195	0.274	< 0.3	+	+	+	+	+	+
Stench	Ordered	0.047	–0.566	0.273	0.602	< 0.3	+	+	+	+	+	+
Putrid	Ordered	0.745	–0.465	0.404	0.525	< 0.3	+	+	+	+	+	+
Sickening	Ordered	0.906	0.640	2.591	0.108	< 0.3	+	+	+	+	+	+

continued

TABLE 75 Field test 2: Rasch analysis summary statistics for PU-QOL scale items (*continued*)

Scale items	Threshold	Location	FR	CS	*p*-value	Person–item correlations	DIF age		DIF gender		DIF setting	
							Uniform	Non-uniform	Uniform	Non-uniform	Uniform	Non-uniform
***Sleep scale* (n = 133; 3 Class interval; PSI = 0.719)**												
Comfortable position	Ordered	–0.907	0.777	0.468	0.792	< 0.3	+	+	+	+	+	+
Sleep in one position	Ordered	–0.058	2.639[a]	3.239	0.198	< 0.3	+	+	+	+	+	+
Interrupted sleep	Ordered	0.027	–1.144	9.530	0.009	< 0.3	+	+	+	+	+	+
Not getting amount of sleep needed	Ordered	0.065	–1.789	13.303	0.001[a]	< 0.3	+	+	+	+	+	+
Kept awake	Ordered	0.422	–1.485	6.333	0.042	< 0.3	+	+	+	+	+	+
Trouble falling asleep	Ordered	0.451	1.427	6.838	0.033	< 0.3	+	+	+	+	+	+
***Mobility and movement scale* (n = 130; 3 Class interval; PSI = 0.505)**												
Pushing up to sitting	Ordered	–0.457	–0.123	3.303	0.192	< 0.3	+	+	+	+	+	+
Adjusting in bed	Ordered	–0.349	–0.832	6.928	0.031	0.498	+	+	+	+	+	+
Difficulty sitting	Ordered	–0.155	2.310	0.990	0.610	< 0.3	+	+	+	+	+	+
Difficulty turning/ moving in bed	Ordered	–0.138	–0.454	3.079	0.214	0.498	+	+	+	+	+	+
Walking slowed	Ordered	–0.006	–0.501	6.426	0.040	0.701	+	+	+	+	0.00	+
Difficulty standing for long periods	Disordered	0.165	–0.060	1.008	0.604	< 0.3	+	+	+	+	+	+
Limited in ability to walk	Ordered	0.168	0.198	4.790	0.091	0.701	+	+	+	+	0.00	+
Difficulty transferring	Ordered	0.201	0.747	0.378	0.828	< 0.3	+	+	+	+	+	+
Limited ability to go up/down stairs	Disordered	0.572	0.475	0.954	0.621	< 0.3	+	+	+	+	+	+

Scale items	Threshold	Location	FR	CS	*p*-value	Person–item correlations	DIF age		DIF gender		DIF setting	
							Uniform	Non-uniform	Uniform	Non-uniform	Uniform	Non-uniform
***Activity scale* (n = 95; 2 Class interval; PSI = 0.102)**												
Regular activities	Disordered	–0.299	0.956	0.652	0.419	< 0.3	+	+	+	+	+	+
Washing	Ordered	–0.298	1.564	0.097	0.756	< 0.3	+	+	+	+	+	+
Shopping	Disordered	–0.230	–1.446	1.825	0.177	< 0.3	+	+	+	+	+	+
Toileting	Ordered	–0.125	0.962	0.055	0.815	< 0.3	+	+	+	+	+	+
Dressing	Ordered	–0.003	0.281	5.084	0.024	< 0.3	+	+	+	+	+	+
Jobs around house	Disordered	0.059	–0.814	2.247	0.134	< 0.3	+	+	+	+	+	+
Doing things you enjoy	Ordered	0.334	0.872	2.002	0.157	< 0.3	+	+	+	+	+	+
Being emotionally close	Disordered	0.561	–0.263	1.642	0.200	< 0.3	+	+	+	+	+	+
***Vitality scale* (n = 98; 2 Class interval; PSI = 0.557)**												
Tired	Ordered	–0.500	–0.327	0.992	0.319	0.49	+	+	+	+	+	+
Fatigued	Ordered	–0.493	–2.177	7.987	0.005	0.49	+	+	+	+	+	+
Energy reduced	Ordered	–0.148	0.104	0.824	0.364	< 0.3	+	+	+	+	+	+
Unwell/poorly	Ordered	0.338	1.624	0.415	0.521	< 0.3	0.00	+	+	+	+	+
Appetite reduced	Ordered	0.804	1.133	1.164	0.281	< 0.3	+	+	+	+	+	+

continued

TABLE 75 Field test 2: Rasch analysis summary statistics for PU-QOL scale items (*continued*)

Scale items	Threshold	Location	FR	CS	*p*-value	Person–item correlations	DIF age		DIF gender		DIF setting	
							Uniform	Non-uniform	Uniform	Non-uniform	Uniform	Non-uniform
Emotional well-being scale **(n = *181; 4 Class interval; PSI = 0.846*)**												
Fed up	Ordered	–1.478	1.109	2.428	0.489	< 0.3	+	+	+	+	+	+
Frustrated	Ordered	–1.055	–1.298	9.373	0.025	< 0.3	+	+	+	+	+	+
Annoyed/irritated	Ordered	–0.673	1.542	4.816	0.186	< 0.3	+	+	+	+	+	+
Physically dependent	Ordered	–0.598	0.558	2.208	0.530	< 0.3	+	+	+	+	+	+
Miserable	Ordered	–0.441	–1.073	7.850	0.049	< 0.3	+	+	+	+	+	+
Anxious	Ordered	–0.298	1.223	7.749	0.052	0.560	+	+	+	+	+	+
No control	Ordered	–0.120	–2.261	7.078	0.069	< 0.3	+	+	+	+	+	+
Burden/nuisance	Ordered	–0.113	–0.096	3.332	0.343	< 0.3	+	+	+	+	+	+
Concerned/worried	Ordered	–0.104	0.795	0.719	0.867	0.560	+	+	+	+	+	+
Angry	Disordered	0.164	–0.735	4.103	0.250	< 0.3	+	+	+	+	+	+
Missing out	Ordered	0.223	–1.209	5.481	0.140	< 0.3	+	+	+	+	+	+
Depressed	Ordered	0.235	–2.361	9.588	0.022	< 0.3	+	+	+	+	+	+
Lonely	Ordered	0.891	–0.832	1.770	0.621	0.519	+	+	+	+	+	+
Cut off/isolated	Ordered	0.926	–1.345	3.520	0.318	0.519	+	+	+	+	+	+
Others avoided	Disordered	2.442	0.117	5.294	0.152	< 0.3	+	+	+	+	+	+

Scale items	Threshold	Location	FR	CS	*p*-value	Person–item correlations	DIF age		DIF gender		DIF setting	
							Uniform	Non-uniform	Uniform	Non-uniform	Uniform	Non-uniform
Self-consciousness and appearance scale* (n = *100; 2 Class interval; PSI = 0.529)												
Helpless	Ordered	–1.268	–0.517	0.784	0.376	< 0.3	+	+	+	+	+	+
Lacking confidence	Ordered	–0.654	–0.025	0.143	0.705	< 0.3	+	+	+	+	+	+
Self-conscious	Ordered	–0.465	0.114	1.388	0.239	0.415	+	+	+	+	+	+
Embarrassed	Ordered	–0.290	0.077	0.731	0.393	0.415	+	+	+	+	+	+
Feeling physically unattractive	Ordered	0.727	–1.131	3.061	0.080	< 0.3	+	+	+	+	+	+
Lack understanding from others	Ordered	0.928	1.137	4.227	0.040	< 0.3	+	+	+	+	+	+
Uneasy being close to others	Ordered	1.022	–0.283	1.007	0.315	< 0.3	+	+	+	+	+	+
Participation scale* (n = *82; 2 Class interval; PSI = 0.435)												
Restricted where you go out	Disordered	–0.912	–0.962	2.095	0.148	< 0.3	+	+	+	+	+	+
Difficulty going out	Ordered	–0.877	–0.801	0.991	0.319	< 0.3	+	+	+	+	+	+
Restricted how you long stay out	Disordered	–0.664	–0.227	0.424	0.515	< 0.3	+	+	+	+	+	+
Holiday/weekend	Disordered	–0.016	0.403	0.690	0.406	< 0.3	+	+	+	+	+	+
Give up hobbies/ leisure	Disordered	0.188	–0.387	1.193	0.275	< 0.3	+	+	+	+	+	+
Participate family gatherings	Disordered	0.356	0.342	0.689	0.407	0.694	+	+	+	+	+	+
Meeting family/ friends	Disordered	0.428	0.116	0.156	0.693	0.694	+	+	+	+	+	+
Plan going out around PU care	Disordered	0.501	0.163	0.151	0.698	< 0.3	+	+	+	+	+	+
Time involved caring for PU	Ordered	0.995	0.387	0.608	0.436	< 0.3	+	+	+	+	+	+

+, no DIF detected; CS, chi square; FR, fit residual; PSI, person separation index with extremes; PU, pressure ulcer.
a Indicates values outside the recommended range (i.e. item misfit).

Traditional psychometric analysis

The traditional psychometric analysis supported the final PU-QOL scales as being reliable and valid measures of pressure ulcer symptoms, physical and social functioning and psychological well-being. The criteria were satisfied for most psychometric properties evaluated. Briefly, data quality was high (scale scores were computable for 95.6–99.6% of respondents; *Table 76*) and scaling assumptions were satisfied (mean scale scores and SDs were mostly similar to scale mid-points; *Table 77*). All item–own scale correlations were high (corrected ITC ranges 0.511–0.940; see *Table 77*), satisfying the recommended criterion (> 0.3), thus providing support that items within scales measured a common underlying construct (a corrected ITC > 0.3 indicates that items within each scale contain a similar proportion of information).

Scale-to-sample targeting was good, apart from where skew was clinically reasonable [scale scores spanned the scale range but were notably skewed for four scales (value outside ±1.0), mean scores were near the scale mid-point for 6 out of 10 scales and ceiling effects were negligible; however, floor effects exceeded the 15% criterion for 4 out of 10 scales; see *Table 76*]. Internal consistency reliability was high, as demonstrated by Cronbach's alpha values for all PU-QOL scales exceeding the standard criterion of 0.7 (range 0.893–0.969; see *Table 77*). ITCs ranged from 0.511 to 0.940, fulfilling the recommended criterion of > 0.3. Finally, test–retest correlations for eight out of 10 scales exceeded 0.7 (see *Table 77*); two scales had correlations below the recommended criterion, but marginally, thus mostly fulfilling the recommended minimum criteria and indicating good scale stability.

TABLE 76 Pressure Ulcer Quality of Life instrument scale-level analyses: data completeness and targeting ($n = 229$)

Scale	Data completeness	Targeting						
	Computable scale score (%)	Possible score (range)[a]	Range mid-point	Observed score (range)	Mean score	SD	F/C effect (%)[b]	Skewness
Pain	95.6	0–16	8	0–16	6.14	4.586	15.2/3.9	0.396
Exudate	98.3	0–15	7.5	0–15	2.09	3.494	57.0/0.9	1.898
Odour	99.6	0–12	6	0–12	0.97	2.850	83.0/4.3	3.144
Sleep	99.6	0–12	6	0–12	4.66	4.302	10.7/4.1	0.434
Vitality	98.3	0–10	5	0–10	2.72	3.217	27.0/2.2	0.896
Mobility	97.8	0–18	9	0–17	7.08	5.377	1.5/0.4	0.362
Daily activities	95.6	0–16	8	0–14	3.67	4.389	3.9/0.4	1.058
Emotional Well-being	95.2	0–30	15	0–28	10.15	9.190	8.3/1.3	0.673
Appearance & self-consciousness	96.5	0–14	7	0–14	2.53	3.632	38.7/2.2	1.566
Participation	95.6	0–18	9	0–18	5.66	6.264	6.2/0.4	0.587

F/C, floor/ceiling.
a High scores indicate great bother/impact.
b Floor effect = % scoring 100 (greatest bother/impact); ceiling effect = % scoring 0 (least bother/impact).

TABLE 77 Pressure Ulcer Quality of Life instrument scale-level analyses: reliability, scaling assumptions and validity within-scale analysis ($n = 229$)

Scale	Internal consistency (Cronbach's alpha)	SEM	95% CI	Mean IIC	IIC (range)	Scaling assumptions (corrected ITC) (range)	Test–retest reproducibility		
							ICC consistency	ICC absolute	Correlation
Pain	0.893	0.453	6.50 to 8.29	0.482	0.235–0.663	0.525–0.703	0.803	0.805	0.804
Exudate	0.907	0.233	1.63 to 2.55	0.544	0.316–0.715	0.511–0.752	0.622	0.625	0.622
Odour	0.969	0.187	0.60 to 1.35	0.841	0.716–0.934	0.794–0.940	0.681	0.680	0.700
Sleep	0.920	0.327	4.01 to 5.30	0.657	0.491–0.805	0.681–0.846	0.822	0.816	0.824
Vitality	0.900	0.275	2.18 to 3.27	0.638	0.488–0.902	0.628–0.898	0.735	0.738	0.736
Mobility	0.927	1.069	6.20 to 10.59	0.586	0.226–0.912	0.666–0.799	0.873	0.864	0.879
Daily activities	0.952	1.374	4.83 to 10.57	0.710	0.407–0.904	0.583–0.899	0.866	0.872	0.870
Emotional Well-being	0.934	0.931	9.71 to 13.42	0.486	0.242–0.780	0.537–0.761	0.829	0.820	0.832
Appearance & self-consciousness	0.894	0.271	1.99 to 3.07	0.557	0.371–0.789	0.617–0.755	0.812	0.814	0.814
Participation	0.932	0.719	4.23 to 7.09	0.601	0.359–0.877	0.599–0.861	0.627	0.639	0.634

ICC, intraclass correlation; IIC, inter-item correlation; SEM, standard error of the mean.

Evidence of the internal construct validity of the PU-QOL scales is provided by moderate to high ITCs, high Cronbach's alpha values and moderate to high inter-item correlations (means > 0.48 and ranges between 0.226 and 0.934 indicate that PU-QOL scale items were mostly correlated with scale scores; see *Table 77*), indicating that each scale measures a single construct. Correlations between PU-QOL scales and hypothesised related scales of the SF-12 were consistent with most predictions (*Table 78*), providing support for PU-QOL scales measuring what they intend to measure; moderate to high correlations ($r > 0.30$) were predicted. Correlations between PU-QOL scales and sociodemographic variables (age, gender) were consistent with predictions ($r < 0.30$; see *Table 78*), thus suggesting that responses to PU-QOL scales are not biased by age or gender.

The scales for exudate and odour were able to differentiate known groups as predicted; a significant step increase in mean score by pressure ulcer severity groups was observed (see *Table 78*). All other tests of known group differences were considered exploratory; significant step increases were observed in scores for the scales measuring vitality, daily activities, emotional well-being and self-consciousness when patients were grouped by pressure ulcer severity. In contrast, no step increase in scores was observed for the scales measuring pain, sleep, mobility and movement and participation. For all scales apart from the sleep scale, the mean score on HRQoL outcomes for category 1 ulcers was lower than that for category 3/4 ulcers, suggesting that HRQoL outcomes are worse for people with severe ulcers than for those with superficial category 1 ulcers. It is important to note that the category 1 ulcer sample sizes were small (range 4–14 patients) and therefore the known groups validity results are preliminary and further empirical evidence is required to have confidence that the PU-QOL scales can detect small differences in the constructs being measured.

Final Pressure Ulcer Quality of Life instrument

The final version of the PU-QOL consists of 10 scales (82 items) measuring symptoms, physical functioning, psychological well-being and social participation specific to pressure ulcers [see *Appendix 43*; the final PU-QOL instrument can be accessed at http://medhealth.leeds.ac.uk/puqol-ques (accessed July 2015)]. An additional item is included to assess pain severity. There are three symptom scales measuring pain (eight items plus one descriptive pain severity item), exudate (eight items) and odour (six items) and one descriptive itchiness item; four physical functioning scales measuring sleep (six items), movement and mobility (nine items), daily activities (eight items) and vitality (five items); two psychological well-being scales measuring emotional well-being (15 items) and self-consciousness and appearance (seven items); and one social participation scale (nine items). Patients rate the amount of 'bother' attributed (e.g. 'During the past week, how much have you been bothered by . . . because of your pressure sore?') on a 3-point response scale (0 = no bother; 1 = little bother; 2 = a lot of bother). In addition, respondents are given an alternative response option enabling them to state that they are affected by the issue described in the item but that it is not related to their ulcer ('I have this problem but not because of my pressure ulcer'); this is treated as descriptive information and is not part of the scale score. Scales can be selected for use depending on the nature of the research and scale items can be summed to produce scores, without weighting or standardisation. Scores for each domain are calculated as the sum of each individual item score within that scale, which is then converted to a metric of 0–100; a lower score indicates better outcome. Imputation of missing data, based on methods undertaken for scoring the Short Form questionnaire-36 items (SF-36),[270] can be undertaken, provided that at least 50% of items are complete for an individual.

The PU-QOL instrument is appropriate for use in adults across the range of levels of pressure ulcer severity and type (location and duration) and UK health-care settings and is suitable for group comparison. It is intended for interview administration, supported by a user manual providing practical information necessary for administration and scoring. The PU-QOL instrument and user manual are freely available through the University of Leeds CTRU website [see http://medhealth.leeds.ac.uk/puqol-ques (accessed July 2015)].

TABLE 78 Pressure Ulcer Quality of Life scale-level analyses: validity ($n = 229$)

	Convergent validity								Discriminant validity		Known groups[c] – PU severity[d]	
Scale	SF-12 PF scale r[a]	SF-12 SF scale r[a]	SF-12 RF scale r[a]	SF-12 MH scale r[a]	SF-12 pain item r[a]	SF-12 fatigue item r[a]	PU-QOL pain item r[a]	PU-QOL QOL item r[a] (n)	Gender r[b] (n)	Age r[b] (n)	Mean score (n)	p-value (95% CI)
Pain	–0.03	–0.08	–0.13	–0.04	0.48[e,f]	0.06	0.79[f]	0.38[f] (206)	0.13[f] (214)	0.11[f] (214)		0.895
Category 1											5.36 (14)	(2.85 to 7.86)
Category 2											5.81 (77)	(4.78 to 6.83)
Category 3/4											5.51 (68)	(4.49 to 6.54)
Exudate	–	–	–	–	–	–	–	0.25[g] (216)	0.08[f] (225)	–0.14[f] (224)		0.000[h]
Category 1											0.64 (14)	(–0.43 to 1.72)
Category 2											1.07 (81)	(0.55 to 1.60)
Category 3/4											3.26 (72)	(2.31 to 4.21)
Odour	–	–	–	–	–	–	–	0.20[g] (217)	0.05[f] (228)	–0.14[f] (227)		0.004[h]
Category 1											0.07 (14)	(–0.08 to 0.23)
Category 2											0.28 (82)	(–0.05 to 0.61)
Category 3/4											1.60 (72)	(0.77 to 2.43)
Sleep	–	–	–	–	–	–	–	0.32[f] (171)	0.21[f] (178)	0.10[f] (178)		0.774
Category 1											4.89 (9)	(1.36 to 8.42)
Category 2											4.49 (65)	(3.41 to 5.57)
Category 3/4											4.02 (54)	(2.84 to 5.20)
Vitality	–0.24[e]	–0.12	–0.37[e]	–0.01	0.37[e]	0.36[f]	–	0.52[f] (135)	0.03[f] (137)	–0.16[f] (137)		0.036[h]
Category 1											1.22 (9)	(–0.40 to 2.84)
Category 2											1.82 (50)	(1.02 to 2.62)
Category 3/4											3.25 (48)	(2.26 to 4.24)

continued

TABLE 78 Pressure Ulcer Quality of Life scale-level analyses: validity ($n = 229$) (*continued*)

	Convergent validity								Discriminant validity		Known groups[c] – PU severity[d]	
Scale	SF-12 PF scale r[a]	SF-12 SF scale r[a]	SF-12 RF scale r[a]	SF-12 MH scale r[a]	SF-12 pain item r[a]	SF-12 fatigue item r[a]	PU-QOL pain item r[a]	PU-QOL QOL item r[a] (n)	Gender r[b] (n)	Age r[b] (n)	Mean score (n)	p-value (95% CI)
Mobility	–0.49[e]	–0.30	–0.45[e]	–0.10	0.40[h]	0.49[e]	–	0.39[f] (37)	0.04[f] (39)	0.22[f] (39)		0.137
Category 1											5.00 (4)	(–1.62 to 11.62)
Category 2											4.36 (11)	(1.94 to 6.79)
Category 3/4											8.31 (13)	(4.82 to 11.80)
ADL	–0.39[h]	–0.36[h]	–0.389[e]	–0.17	0.53[e]	0.14	–	0.35[f] (48)	–0.05[f] (49)	–0.19[f] (49)		0.094
Category 1											1.60 (5)	(–0.66 to 3.86)
Category 2											1.73 (11)	(–1.06 to 4.51)
Category 3/4											4.63 (24)	(2.81 to 6.44)
EWB	–0.21[h]	–0.25[e]	–0.37[e]	–0.44[h]	0.29[e]	0.38[e]	–	0.58[f] (133)	0.16[f] (135)	–0.15[f] (135)		0.001[h]
Category 1											4.13 (8)	(1.39 to 6.86)
Category 2											7.41 (46)	(4.98 to 9.84)
Category 3/4											13.28 (47)	(10.39 to 16.16)
ASC	–0.22[e]	–0.30[e]	–0.29[e]	–0.40[h]	0.32[e]	0.23[e]	–	0.50[f] (176)	0.23[f] (179)	–0.03[f] (178)		0.014[h]
Category 1											0.92 (12)	(–0.42 to 2.26)
Category 2											1.85 (62)	(1.02 to 2.68)
Category 3/4											2.52 (58)	(2.43 to 4.71)

Scale	Convergent validity								Discriminant validity		Known groups[c] – PU severity[d]	
	SF-12 PF scale r[a]	SF-12 SF scale r[a]	SF-12 RF scale r[a]	SF-12 MH scale r[a]	SF-12 pain item r[a]	SF-12 fatigue item r[a]	PU-QOL pain item r[a]	PU-QOL QOL item r[a] (n)	Gender r[b] (n)	Age r[b] (n)	Mean score (n)	p-value (95% CI)
Social participation	–0.34[e]	–0.46[e]	–0.38[e]	–0.07	0.03	0.26[h]	–	0.51[f] (75)	0.01[f] (76)	–0.29[f] (76)		0.018[h]
Category 1											3.67 (6)	(–1.55 to 8.88)
Category 2											2.55 (22)	(0.43 to 4.66)
Category 3/4											7.35 (31)	(4.84 to 9.87)

ASC, appearance and self-consciousness; EWB, emotional well-being; MH, mental health; PF, physical function; PU, pressure ulcer; QOL, quality of life; RF, role physical; SF, social function; SP, social participation.

a Spearman correlation.
b Pearson correlation.
c ANOVA.
d PU severity categorised into three PU groups: category 1; category 2; categories 3/4 combined.
e Significant at $p = 0.05$ (two-tailed).
f Correlations consistent with predictions.
g Correlations falling outside of the predicted range.
h Significant at $p = 0.01$ (two-tailed).

Discussion

This research established the impact of pressure ulcers on HRQoL, determined the need for a pressure ulcer-specific PRO instrument and developed and psychometrically evaluated such an instrument. In our work predating the PURPOSE programme we systematically reviewed the HRQoL literature in the pressure ulcer field and found that it is mainly qualitative with an emphasis on pain and physical functioning impairment rather than a comprehensive exploration of issues that are important to patients.[9] Potential sources of bias arise because of the use of small sample sizes ($n \leq 10$) and under-representation of people with superficial ulcers, the elderly (aged > 70 years) and those acutely ill or with various comorbidities. Some HRQoL outcomes that are unique to pressure ulceration were highlighted but these outcomes are currently not systematically included as outcomes in clinical trials. Therefore, the pressure ulcer literature is unconvincing in terms of robust evaluation of the impact of pressure ulcers and treatments on HRQoL (i.e. quantitative studies designed to explore HRQoL in pressure ulceration had used measures not developed or validated for use with patients with pressure ulcers).[216] Further, no pressure ulcer-specific PRO instruments exist,[216] highlighting the need for outcome measures that can accurately depict the impact of pressure ulcers on HRQoL.

The PU-QOL instrument was developed to provide a formal method for capturing issues that are most important to patients with pressure ulcers from their perspectives. New instrument construction needs to be underpinned with a strong conceptual base to ensure valid measurement, one that adequately defines the variables and relationships conceptually and gives operational meaning that guides the development (or selection) of PRO instruments.[212] Building on our earlier work[9] we found that pressure ulcers impact all aspects of HRQoL, severely compromise patient functioning and cause significant burden, pain and increased discomfort as a result of treatment.[36,221] We developed a pressure ulcer-specific conceptual framework of HRQoL that includes conceptual domains for symptoms; difficulty with range of movement and mobility; limitations in daily activities; psychological functioning; and ability to participate socially.[221] These constructs are similar to those in generic HRQoL models;[206,271,272] however, our framework incorporates additional components specific to pressure ulceration (e.g. symptoms; appearance and self-consciousness). The development of our conceptual framework was hampered by the poor quality and quantity of the existing literature[9] and required further qualitative interviews with patients and consultation with experts. Elucidation of conceptual domains that are important to patients with pressure ulcers provides a useful framework for designing future research and consequently improving the quality of research in the pressure ulcer field by inclusion of a pressure ulcer-specific PRO instrument.

Mixed methods, including feedback from patients through cognitive interviews and a Rasch analysis of PU-QOL data, were effective for identifying problems with PU-QOL items early in the development process. Overall, patient input was the most important element of the development process. Despite undertaking two systematic reviews of the literature (pressure ulcer pain and existing chronic wound PRO instruments) intended to generate items, only a few descriptive words for pressure ulcer-related pain were added to the item pool; the majority of the item content was generated from patient interviews. The empirically derived pressure ulcer-specific conceptual framework informed the development of the PU-QOL instrument.

Scale development and item reduction were primarily guided by RMT, which provided a vehicle for the detection of items deviating from model expectations with the intention of improving scale attributes. Final decisions on item inclusion were made according to appraisals of the analyses of the observed data against measurement criteria and clinical relevance, as opposed to examinations carried out singularly or sequentially. A preliminary evaluation of the Rasch-produced scales using traditional psychometric methods supported the PU-QOL instrument as being reliable and valid. In addition, an empirical investigation of the optimal mode of administration of the PU-QOL instrument revealed that self-completion was not suitable for patients with pressure ulcers. Consequently, the mode of administration was changed to interview administered to ensure that the PU-QOL instrument would be applicable to a wider range of people with pressure ulcers and potentially yield higher-quality data.

The final psychometric evaluation supported the PU-QOL scales as being valid and reliable for use in clinical trials according to US FDA criteria;[212] however, some important limitations were identified. The Rasch analysis highlighted that further work is required before the PU-QOL scales can be used as the main PRO measure in future clinical trials or other research. Measurement precision could be improved by developing items that span a wider measurement range and, in the process, maximising the potential of the PU-QOL instrument to detect change. The appropriateness of the PU-QOL instrument for use in individual decision-making requires further investigation. The measurement precision may need strengthening to enable assessment of individual patients in clinical practice (e.g. revisit the qualitative work to add items to extend the measurement at the floor/ceiling scale range; further work to ensure that the PU-QOL scales differentiate between different levels of ulcer severity). Longitudinal studies should be undertaken to assess the responsiveness of the PU-QOL instrument over time and following treatment, as clinical studies evaluating the effectiveness of various ulcer treatments and interventions require accurate detection of true change. Further research is also needed to investigate self-completion and electronic (e.g. ePRO) mode of administration methods, the feasibility of use in specific subgroups, support for score interpretation and the utility of the PU-QOL instrument in routine practice; to develop proxy measures and language translations given the prevalence of cognitively impaired patients with pressure ulcers (e.g. almost 40% of screened patients in field test 1 and 30% in field test 2 were ineligible because of cognitive impairment, consistent with findings from the pain prevalence study;[48] see *Chapter 3*); and to carry out an economic evaluation (see *Chapter 7*).

The final PU-QOL instrument consists of independent scales for assessing symptoms and physical, psychological and social functioning specific to pressure ulcers. The PU-QOL instrument can be included as one outcome measure among others in future pressure ulcer research on the proviso that studies have built in a parallel psychometric analysis to indicate the performance (psychometric evaluation) of the scales in future samples. Currently, the PU-QOL scales are most appropriate for patients with severe pressure ulcers, as demonstrated by a lack of items to represent people with little or no bother as a result of pressure ulcers. The exudate and odour scales are not intended for people with superficial ulcers (category 1).

The PU-QOL instrument provides a means to comprehensively assess the impact of pressure ulcers and a way of quantifying the benefits of ulcer interventions. It may also provide a key to discussions between health-care providers and patients about impact that are currently not being held. Patients in our interviews repeatedly reflected on their relationship with their tissue viability nurse, stating that the issues discussed during our interviews were not issues that they had previously discussed with their nurse. The lack of inclusion of HRQoL outcomes in previous pressure ulcer research is supported by the literature. Thus, PU-QOL data could facilitate patient–health-care provider communication and increase understanding of the impact of pressure ulcers on individuals, which ultimately could lead to adjustments in care delivery to meet patient needs. They may also highlight important patient-orientated differences between interventions to justify resource allocation. This is particularly important for changing practice through mandated NICE guidance. Specifically, the perceived value of pressure ulcer interventions and evaluating PROs associated with treatment and relative burden must have a robust evidence base[212,224,273] to help inform decisions about the most appropriate ulcer management, policies and health-care delivery in the pressure ulcer field.

Methodological issues and study limitations

This is the first outcome measure specific to pressure ulcers, reflecting the domains in a pressure ulcer-specific conceptual framework of HRQoL outcomes, content that differs from that for other chronic wounds. However, this study had some limitations. In the qualitative phase of PU-QOL development, in-depth interviews were used to develop and refine the content of the scales. Additional qualitative methods such as focus groups and interviews with the carers of people with pressure ulcers may have provided a further opportunity to combine findings. Further, the questioning was intended to elicit the worst aspect of having a pressure ulcer. This line of questioning may have resulted in valuable information about patient experiences when pressure ulcer symptoms and other aspects are managed well being missed. Better use of qualitative questioning would have resulted in the inclusion of patients with healed or close to healed pressure ulcers, asking them asked about the entirety of their experience, with more

thought given to covering the full spectrum of the pressure ulcer experience (e.g. experience of when treatment was effective and when pressure ulcer impact was milder/not at its worst and words to describe the benefit/ulcer improvement). This may have helped to improve the measurement range by including items that represented milder ulcer impact/bother.

The validity testing of the PU-QOL scales was limited, in part by a lack of appropriate validating measures and the inability to formulate hypotheses to enable known group difference testing. The literature is limited about the roles that pressure ulcer severity, duration and location play in affecting HRQoL outcomes. Such gaps in knowledge limit the ability to develop strong hypotheses to evaluate known group validity. Further, the SF-12v2 is a generic measure that has not been developed or validated for use with people with pressure ulcers. Given the uncertainty about the appropriateness of the SF-12 for use with people with pressure ulcers, this was included in the validation process on an exploratory basis.

Pressure Ulcer Research Service User Network UK

Pressure Ulcer Research Service User Network UK members were involved in reviewing the different versions of the PU-QOL instrument and associated materials throughout the development process. One of the considerations when developing the PU-QOL user manual was ensuring that the instrument itself is used in a way that is acceptable to patients. With that in mind, PURSUN UK members were invited to review the manual. To help facilitate this review process, the researcher set a series of questions designed to help guide people through a fairly complex document.

Members were also asked to give general comments about the PU-QOL instrument itself. Comments made highlighted:

- the importance of reassuring patients that there is no right or wrong answer and that their perception is what is important
- areas that could be clearer (e.g. instructions)
- the importance of anonymity for this particular population and the need to be clear about how the results of the instrument will be used.

Throughout the review process, the perspective of PURSUN UK has been balanced with the need to adhere to international guidelines on the development of outcome measures. This required an open dialogue between members and the researcher. PURSUN UK members said that they valued the fact that the researcher was honest about aspects that could not be changed and gave clear reasons for this rather than simply disregarding their input.

Conclusion

This study makes important contributions to the pressure ulcer and wider health measurement fields. The PU-QOL instrument provides a means to comprehensively assess pressure ulcer impact and quantify the benefits of pressure ulcer interventions from the patient perspective for research use, thus far lacking in this area. Scientifically rigorous PRO measurement needs to become more commonplace in the pressure ulcer field so that the goal of pressure ulcer management can be to enhance and maintain the HRQoL of people with pressure ulcers. Subject to further development, the PU-QOL instrument is a tool that can be used to evaluate whether or not pressure ulcer treatments and the health care given achieve this, outcomes that are ultimately best judged by patients themselves. Future use of the PU-QOL instrument will provide the data necessary for its further development.

Chapter 7 Deriving a preference-based measure for use in cost–utility analyses of pressure ulcer interventions

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Abstract

Introduction: Cost–utility analysis has become the gold standard for economic evaluation. In some therapeutic areas where the use of the European Quality of Life-5 Dimensions (EQ-5D) is found to be inappropriate, condition-specific utility measures are developed with the aim of providing a more accurate assessment of the impact of conditions and to provide a more sensitive measure of the benefit of interventions. The aim of this study was to create a preference-based index from the PU-QOL instrument that could be used to generate utility values suitable for use in cost–utility-based economic evaluations.

Methods: The methods employed to achieve this followed those used to value the three-level EQ-5D. Specifically, we conducted time trade-off task valuations of health states derived from selected PU-QOL items with a sample ($n = 200$) of the general population. A secondary study was conducted to validate the item selection and assess the psychometrics of the new index.

Results: Seven items were selected from the PU-QOL instrument for inclusion in the index on the basis of best practice psychometric and Rasch methods. Of the large number of potential health states constructed from the items and response option variants, 52 were valued by the general population with the remaining health state values being predicted using ordinary least squares and random-effects regression models. Although both models exhibited satisfactory predictive power and acceptably low levels of error, the random-effects model is recommended for use. The secondary study analysis indicated that item selection for the PUQOL-UI was appropriate and that the index was acceptable to patients and had adequate levels of validity.

Conclusions: The PUQOL-UI is a seven-item instrument that will complement the PU-QOL instrument and will deliver pressure ulcer-specific utility values for use in cost–utility analysis.

Introduction

In this chapter we report the design, implementation and analysis of a valuation study for the PUQOL-UI, undertaken to facilitate the use of the PU-QOL instrument (see *Chapter 6*) as an outcome measure in clinical trials of pressure ulcer prevention and treatment interventions, by supporting its use in cost-effectiveness analyses. The chapter starts by providing some background on cost-effectiveness analysis for health-care resource allocation and the use of generic compared with condition-specific utility measures (CSUMs) in this context. It then goes on to describe the PU-QOL instrument, the process of identifying a short-form version and additional changes to the response format used in the PU-QOL, to develop a measure that it would be feasible to use in a health state valuation study. This is followed by a description of the design and implementation of the health state valuation study and analysis of the data obtained to produce a health state utility algorithm for the PU-QOL instrument. The fourth chapter component describes a study that was conducted to test the PUQOL-UI item selection and provide an assessment of the psychometric properties of the measure. The strengths and weaknesses of the research and priorities for further work are outlined in the discussion.

Cost-effectiveness analysis for health-care resource allocation

Cost–utility analysis has become the gold standard for economic evaluation in many countries as it allows a combined evaluation of the cost of health technologies along with a measure of the quality and survival benefits that they confer. Another important advantage of cost–utility analysis is that it allows the comparison of technology cost-effectiveness across therapeutic areas. The most common way to capture health state utility values for use in cost–utility analysis is to employ multi-attribute utility questionnaires. Such multi-attribute utility instruments as the EQ-5D,[274] Short Form questionnaire-6 Dimensions (SF-6D)[275] and Health Utilities Index (HUI)[276] are commonly included in clinical studies for this purpose. Utility (or 'preference-based') measures typically produce a range of values from 1, representing full or perfect health, through 0, representing death, to minus infinity, with negative values denoting health states considered worse than death. These utility value weights are combined with survival information to calculate quality-adjusted life-years (QALYs), which are the basis of cost–utility analysis. One year spent in a health state of full or perfect health (utility = 1) is equal to 1 QALY.

In its updated health technology appraisal guidance, NICE[273] states that health effects for cost-effectiveness analyses should be expressed in terms of QALYs and that the EQ-5D is the preferred utility measure on which QALYs should be based. As different utility measures may yield substantively divergent utility values for the same individual, the use of a common metric and tool with which to measure it is necessary to ensure that comparative analyses and resource allocation decisions across therapeutic areas (and time) are possible.

European Quality of Life-5 Dimensions three-level version

The EQ-5D-3L (EQ-5D three-level version) includes five domains (questions): mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each question has three response options ('no problems', 'some problems' and 'extreme problems') and utility values range from 1 (full health) to –0.59, based on a tariff scoring system generated in the UK.[277] Although the EQ-5D is quick and relatively easy to complete, its lack of breadth may mean that it is not a suitable instrument for capturing health effects in some populations. NICE acknowledges this and states that alternatives can be used if there is evidence that the EQ-5D lacks content or construct validity or responsiveness in the target population. These shortcomings may be present in patients with pressure ulcers. A qualitative examination of the impact of pressure ulceration on patient quality of life (see *Chapter 6*, *Qualitative study*)[221] suggests that there are a number of domains of relevance to patients that are omitted from the EQ-5D. These include ulcer smell and exudate, general malaise, fatigue and sleep impairment and a significant emotional and social impact encompassing self-consciousness and social isolation. Furthermore, at least one item is inappropriate for a proportion of people with pressure ulcers, specifically those using wheelchairs. Typically, people with pressure ulcers have an antecedent condition that impairs mobility, which can then lead to the development of ulcers. A potentially high proportion of this group will use wheelchairs and this subgroup of patients may find it difficult to answer the EQ-5D mobility question (with response options 'I have no problems walking about', 'I have some problems walking about', 'I am confined to bed'). Although wheelchair users have significant problems walking, they are not confined to bed; thus, the item is invalidated for this group. There are a number of qualitative references highlighting this issue[278–280] although the EuroQol group (understandably) does not permit revisions to the measure to make it more acceptable in this group.[279]

The EQ-5D has rarely been employed in published studies including patients with pressure ulcers[281,282] and an adequate test of the validity of the measure in this group has not yet been conducted. Although there are few data available on the performance of the EQ-5D in pressure ulcer studies, there is evidence that the EQ-5D is unresponsive to health status change in general wound care. For example, Jull and colleagues[283] found that the measure could not distinguish between a group of venous leg ulcer patients whose wounds had and had not healed. Although a new five-level version of the EQ-5D has now been developed, it includes additional response categories and not domains and as such is unlikely to confer better measurement scope in this group than the three-level version.

Condition-specific utility

As a result of limitations of the EQ-5D in some therapeutic areas, a number of CSUMs have been developed from existing condition-specific quality of life measures. These include measures in cancer,[284] incontinence,[285] asthma,[286] mental health,[287] dementia[288] and pulmonary hypertension.[289] The main aim of these CSUMs is to provide a more accurate assessment of the impact of conditions and a more sensitive measure of the benefit of interventions. Although there is a dearth of evidence to corroborate the promise of CSUMs in this regard, the growth in their numbers continues.

Reducing the incidence of pressure ulcers and improving outcomes for those who experience them are key targets for the NHS.[17] To facilitate this there is an identified need to conduct clinical studies of interventions and to establish the value of these interventions.[14,15] However, in view of the potential limits of the EQ-5D as a tool for capturing the health effects of pressure ulcers, there is a clear argument for the development of a CSUM for use in this population. No CSUM currently exists for use in pressure ulcer prevention and care. Alternative sources of utility values are limited to other generic preference-based measures or a predictive algorithm developed using a generic preference-based measure and clinical information,[290] which would not meet the standard of NICE reference case data.[273,291] This chapter describes the generation of a CSUM from the newly developed PU-QOL instrument (see *Chapter 6*). The PU-QOL instrument allows a comprehensive assessment of the impact of pressure ulcers on patients' HRQoL, providing information to help improve patient health care and patient HRQoL and a tool for use in intervention effectiveness research. It is already in use in clinical studies. It is likely that a CSUM, based on the items within the PU-QOL, would provide a more appropriate, valid and sensitive assessment of patients' preferences associated with pressure ulcers than a generic utility measure and would therefore be a more useful tool in cost-effectiveness analysis of associated interventions.

Aim and objective

The aim of this PURPOSE programme work package was to derive a preference-based utility index (PUQOL-UI) from the PU-QOL, enabling the collection of utility values from the PU-QOL and therefore the calculation of QALYs for the purpose of economic evaluation. We also sought to conduct a preliminary validation of the PUQOL-UI.

Research overview

Two studies were conducted in this work package: study A (valuation study) involved the identification of items for inclusion in the PUQOL-UI and the completion of a general population valuation study followed by modelling to identify the PUQOL-UI scoring tariff; study B involved the collection of data from patients using a revised (attribution-free) form of the PU-QOL that would allow verification of item selection and assessment of the psychometric properties of the PUQOL-UI.

Valuation study: general population survey

The generation of a CSUM requires that health states comprising subsets of items from the target measure are 'valued' using preference elicitation techniques (such as the TTO method). Although debate continues about who is the most appropriate source of such values, NICE[273] currently prefers these to come from the general population rather than from patients with the condition in question. This section describes the valuation survey and regression modelling used to generate the PUQOL-UI (see *Appendix 49* for the study protocol).

Aim and objectives

The aim of the valuation study was to derive a preference-based utility index (PUQOL-UI) from the PU-QOL, enabling the collection of pressure ulcer-specific utility values. Specific objectives were to:

1. test the acceptability of a revised form of the PU-QOL with a small group of patients
2. select PU-QOL items for inclusion in the PUQOL-UI
3. design and conduct a valuation survey with the general population
4. conduct analysis to derive the PUQOL-UI scoring tariff.

Methods

The Pressure Ulcer Quality of Life instrument

The PU-QOL instrument is a multidimensional measure of the impact of pressure ulcers on HRQoL (see *Chapter 6* for a full description of the PU-QOL instrument and details on the development work). It includes 83 items and consists of 10 domains covering pain, exudate, odour, sleep, vitality, mobility/movement, ADL, emotional well-being, self-consciousness and appearance and participation outcomes and a single descriptive item on itchiness. Each item has a recall period of 'the past week' and three response options: 'no bother at all', 'a little bother' and 'a lot of bother'. In addition, respondents are given an alternative response enabling them to state that they are affected by the issue described in the item but that it is not related to their ulcer ('I have this problem but not because of my pressure ulcer'). The items and domains were identified on the basis of extensive interviews with patients followed by appropriate field testing. The results of these stages indicate that the PU-QOL instrument has face, content and construct validity and provides a reliable and comprehensive assessment of HRQoL in this group.

The incorporation of the 'attribution' question format was driven by a desire to create a measure that could be used within the individual patient consultation as well as for measuring change at the patient population level. It was also motivated by the fact that pressure ulcers tend to be a corollary of an underlying health condition (which impairs patient mobility) and a desire for pressure ulcer impact not to be subsumed by patients' responses to their general health status (see *Chapter 6*, *Preliminary PU-QOL construction*, for a full justification of this approach). The fact that the PU-QOL instrument asks respondents to focus on the impact associated with their pressure ulcer, requesting that they disregard their general health level, represented a methodological challenge to the generation of the utility index.

The standard approach to health state valuation locates health states described in the descriptive system (the PU-QOL instrument in the current case) on the health utility scale using methods such as TTO and standard gamble. It assumes that all relevant health attributes (i.e. those that will impact on the value attached to health) are captured in the HRQoL descriptive system. Attributable condition-specific measures, such as the PU-QOL instrument, explicitly set aside attributes of health that the respondent does not consider to be impacted by the health condition of interest and thus are not a disaggregation of global health but a disaggregation of one component of global health – those aspects of health that they currently consider to be affected by the condition of interest [the pressure ulcer(s) in the current case].

To relate the information provided by the attributable condition-specific measure to global health in which the QALY scale is anchored, it is necessary to specify the relationship between the condition-specific measure descriptors and the other domains of health that impact on the value attached to a health state. When the domains of health in the attributable condition-specific measure are completely independent of the other domains of global health, then obtaining values for attributable health states would produce estimates of the decrement from full health as a result of the 'attributable condition-specific health status' – in this case the pressure ulcer(s). Thus, a valuation of the PU-QOL in its original format would deliver values representing utility decrements associated with pressure ulcer(s) but not the starting point of the individual on the utility scale. To deal with this issue we created a separate, revised version of the PU-QOL instrument question stem, removing the 'because of your pressure ulcer' attribution, and removed the response option 'I have this problem but not because of my pressure ulcer'.

Study design

Figure 31 (A: valuation study) outlines the stages required for the generation of the utility index. It was first necessary to verify the acceptability of the revised PU-QOL instrument, then select a subset of items for the utility index, generate the health states and conduct the valuation study. The valuation study methods followed those employed in the UK EQ-5D measurement and valuation of health study;[277] specifically, we used the TTO task in a general population sample. Study B (described in *Validation study*) generated data enabling both the psychometric testing of the new utility index and verification of item selection.

Acceptability of the revised Pressure Ulcer Quality of Life instrument

Before the health states were generated for the valuation interviews, it was necessary to check the acceptability of the revised PU-QOL instrument with a small group of people who have experience of pressure ulcers. This involved conducting a small number ($n = 16$) of semistructured, face-to-face interviews with people who currently had or had experienced an ulcer. Participants were recruited through local support groups and PURSUN UK members and were interviewed by an experienced qualitative researcher (see *Appendix 50* for the study information leaflet). Participants completed the revised PU-QOL instrument and were then asked whether or not they found the instrument easy to understand and complete and whether or not there were aspects or questions that they found confusing. Participants were asked specifically whether or not the new question stem (after the removal of the attribution) made sense in each domain. The interview responses were analysed by two qualitative researchers who came to a consensus about the acceptability of the reviewed measure and any necessary changes.

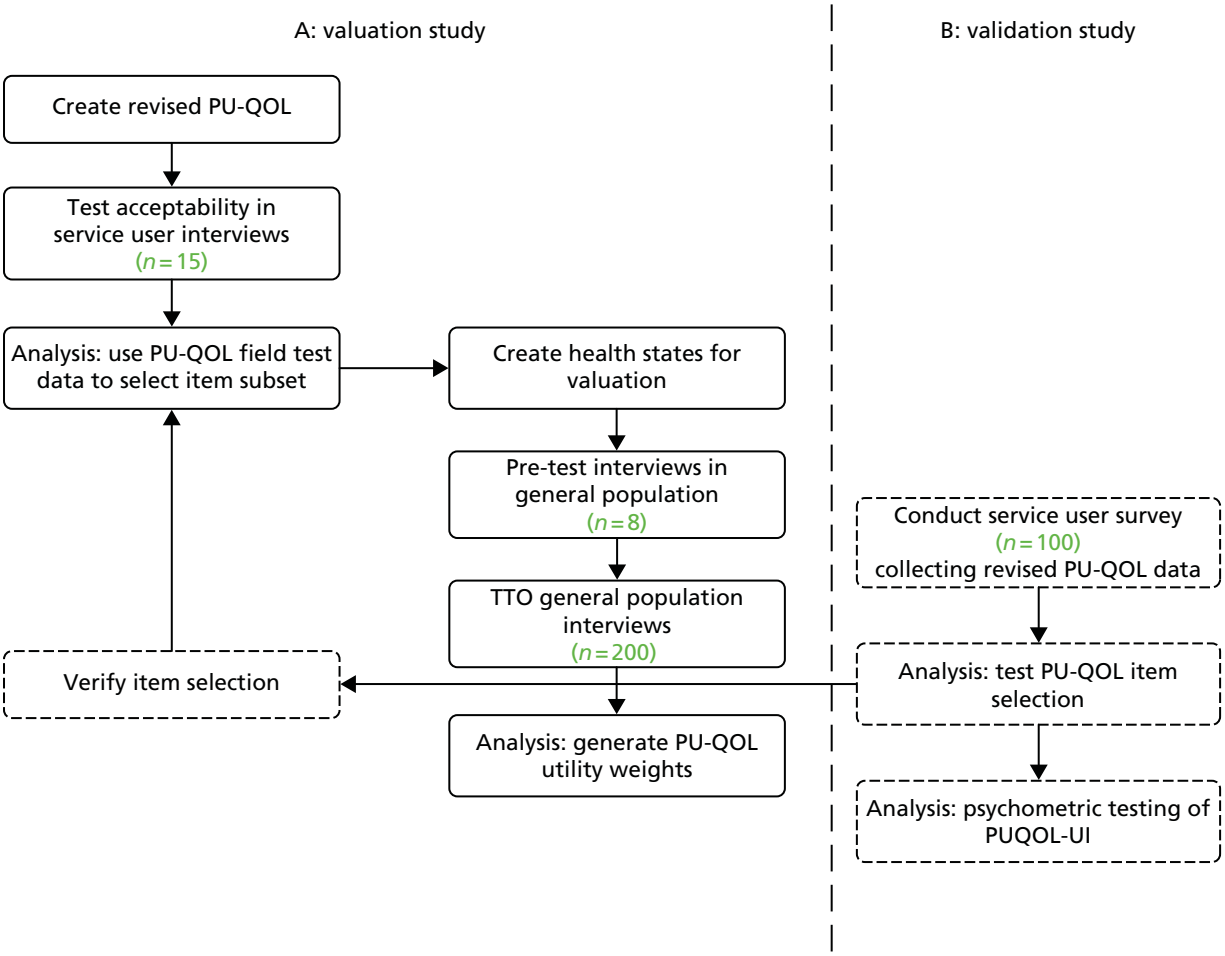

FIGURE 31 Schematic of study design.

Item selection

To generate the health states for valuation it was necessary to identify a reduced version of the instrument as the original PU-QOL instrument had too many potential health states (i.e. $n = 3^{84}$) for direct valuation to be feasible. *Table 79* compares the domains included in the PU-QOL instrument and EQ-5D, highlighting those that could be considered to overlap and those that are unique. The aim of the item reduction process was to select a number of items that captured both the important generic health impact of pressure ulcers and the antecedent health condition and also the more nuanced, condition-specific health impacts associated with pressure ulcers. However, this had to be balanced with how much information is presented in the health states as overburdening valuation survey respondents would lead to poor data quality. Creating a CSUM also requires achieving balance between the inclusion of nuanced items, capturing elements not captured by generic measures, and equally including only items that are important to patients (considering the impact of concurrent health conditions) and that members of the general population would be willing to trade time to ameliorate.

The reduced form was constructed using the methods reported by Brazier and Rowan[292] for the development of a number of CSUMs – including the Asthma Quality of Life – 5 Dimensions instrument[293,294] – and followed best practice recommendations. This involved secondary analysis of the PU-QOL field test 2 data set (see *Chapter 6*, *Phase 3: field testing*) and the use of traditional psychometric and Rasch analyses to identify a reduced PU-QOL instrument (of between seven and 10 items) that incorporated important condition-specific dimensions of the full version. It was necessary to ensure that the items selected represented a range of severity (i.e. not all mild or all severe items), fitted the Rasch model, were valid and had good discriminatory power. *Table 73* describes the data set used for the analysis, generated during field test 2 of the PU-QOL instrument. In field test 2, patients also completed global items on health and the SF-12v2 health status measure, which was converted to SF-6D utility values.[275] Along with these data, information was collected on ulcer category and care setting and demographics. As the PU-QOL instrument is a new instrument there were no available data on its ability to detect change over time (i.e. responsiveness). However, cross-sectional analysis of pressure ulcer category provided a proxy for this desirable attribute.

TABLE 79 Comparison of PU-QOL and EQ-5D domains

PU-QOL domain	Number of items	EQ-5D overlap
Pain	9	✗
Exudate (leakage)	8	
Odour	6	
Sleep	6	
Mobility	9	✗
ADL	8	✗
Vitality	5	
Emotional well-being	15	✗
Self-consciousness and appearance	7	
Social functioning/participation	9	✗
Total	82[a]	

a The single item relating to itch was excluded from analysis as it is descriptive and not scored.

Analysis

Rasch measurement theory[295] is a valuable tool for the development and refinement of instruments and has several advantages over CTT, such as factor analysis[250,296–298] (see *Chapter 6*, *Pre-testing*, *Data analysis* for additional discussion). A Rasch analysis is often employed to identify reduced forms of instruments that will be used in preference valuation studies.[288,299,300] The Rasch model is a special case of the latent-trait item response theory model and places response data for each individual and each item on the same spectrum of severity (logit scale). According to the model, the probability that an individual will respond in a certain way to a particular item is a logistic function of the relative distance between the item location (parameter) and the person location (parameter), and only a function of these two factors. Persons and items are plotted on the same logit scale on the basis of the difference in their location on the underlying spectrum. This difference governs the probability of the expected response for a person, of a given severity, on a question of a given severity. If the observed data do not deviate significantly from the expected responses, then the items fit the Rasch model. The Rasch analysis and traditional psychometric analysis criteria used for item selection are listed in the following sections. A similar method of item selection was employed in the original development and refinement of the PU-QOL instrument, although here we also used factor analysis.

Rasch analysis

- Degree of fit to the Rasch model – chi-square probability and fit residual (items with non-significant chi-square values and residuals $< \pm 2.5$ are candidates for selection).
- Differential item functioning based on age and gender such that bias by these factors is minimised (items with no DIF are candidates for selection).
- Item logit position on each construct's measurement continuum such that items with a range of severity (spanning the entire measurement range) can be identified (items that collectively represent a wide spread of the latent trait are candidates for selection).
- Ordered response category thresholds (items with correctly functioning response categories are candidates for selection).

Traditional psychometric analysis

- Distribution of scores and presence of floor/ceiling effects (items with no floor/ceiling effect are candidates for selection).
- Item–total correlation (items with an ITC of > 0.4 are candidates for selection).
- Principal components factor analyses (items having a moderate to high factor loading within a subscale are candidates for selection).
- Ability to discriminate between pressure ulcer severity groups – *t*-tests for superficial compared with severe ulcer patient scores (highly discriminatory items are candidates).
- Pearson correlations with SF-6D and a global PU-QOL item ['How would you rate your overall quality of life because of your pressure sore(s)'] (items with moderate to high correlations are candidates).

An initial item selection process sought to identify a candidate item from each of the 10 existing PU-QOL instrument domains. A second selection iteration sought to ensure a balance between scope (number of items) and feasibility of valuing the resultant health states, removing items that were not considered of sufficient importance. Results from these analyses were considered together with qualitative information about the relative importance of each item and domain. Members of the PURPOSE team considered the candidate items before reaching a consensus on the items to be included in the PUQOL-UI.

Analyses were conducted in SPSS and RUMM2030.

Valuation

Selection of health states for valuation

The design of health state valuation studies is not currently informed by definitive experimental design theory, but rather by good practice conventions. In line with these conventions, we selected a set of core health states ($n = 37$) for use in the valuation study by constructing an orthogonal array for the PUQOL-UI health state space. This array included the full health state of the PUQOL-UI, which automatically takes the value of 1.0 in the TTO method used for the study, so that one fewer states ($n = 36$) are valued. This orthogonal array was then supplemented with additional states to ensure broad coverage of the health state space described by the PUQOL-UI. To this end, we also selected the following candidate states: the corner states ($n = 7$) of the descriptive system; the inverse corner states ($n = 7$); and the PITS state ($n = 1$), in which each domain of the PUQOL-UI is at level 3 ('a lot of bother'). The corner states are those in which one domain is at the most severe level and all others are at the least severe. In contrast, the inverse corner states place one domain at the lowest level of severity and set all others at the highest level of severity. All states were reviewed for face validity/feasibility and a conventional 'backing-off' procedure was used to identify a feasible health state (i.e. the fewest dimension changes possible were implemented). In the backing-off procedures, five additional health states were created. These were 2222222, 2222122, 2122222, 3332332 and 3232333, where level 1 refers to 'no bother', level 2 to 'a little bother' and level 3 to 'a lot of bother'.

For the purposes of validating the estimated utility models an additional small sample of states was identified using a second orthogonal array. Eight states observed in the second orthogonal array but not in the original array were chosen at random for inclusion in the valuation survey, but not in the estimation sample. In addition to the 51 states already included, this produced a total of 59 states to be valued in the valuation survey.

There is no definitive guidance on the number of observations per state required to estimate utility models, with substantial variation observed in published studies.[274,275,301] Informed by work by one of the authors of the current study, we chose a target of 25 observations per health state on the grounds that the central limit theorem indicates that 25 observations is sufficient to provide a robust estimate of the mean value. This figure is considerably less than that in the UK measurement and valuation of health study[277] but more than that in the UK SF-6D valuation study.

On the basis of experience with previous valuation studies and piloting of the interview schedule (see *Appendix 51*) it was decided to elicit no more than nine valuations from each respondent, to ensure that respondent burden did not impair the quality of the data collected. Surveys were undertaken in 15 distinct geographical regions in the counties of East, West and South Yorkshire and Lincolnshire in the UK. Health state descriptions were randomly allocated across eight batches – four batches consisted of eight health state cards, with the remaining batches using nine health state cards.

Preference elicitation

Preference elicitation was conducted in interviews with a sample ($n = 200$) of the general population. Individuals were recruited door-to-door and offered a £5 voucher as a 'thank you' for participating. Consent was gained from the individuals before they completed the interviews. Interviews were delivered in the home, face-to-face, with responses input directly into a laptop. The screen guided respondents through the tasks, adapting to their responses. However, the interviewer was present to make sure that the respondents understood the task and to answer any queries.

The interview consisted of four sections. In the first section, basic socioeconomic information about the respondent was collected and the respondent was asked to complete the EQ-5D questionnaire. The second section required the respondent to rank the health state cards in the allocated batch, plus their own health and 'dead', from 'worst' to 'best'. Subsequently, they were asked to locate each of these states on a VAS between 0 ('dead') and 100 ('full health'), such that the score and the difference between

scores represented how good or bad they felt a health state was and how much better or worse it was than the health states below and above it on the scale.

The third section of the interview entailed a TTO valuation for each of the states (eight or nine plus one 'test' state) in the allocated batch using a laptop-based TTO sliding scale as a visual prop. The TTO was based on that used in the measurement and valuation of health study,[277] with a 10-year life expectancy.[274] The smallest time increment allowed by the script and prop was 1 month.

The TTO task is a standard economic technique to elicit individuals' strength of preference for various health states.[302] In the TTO task, individuals choose between two certain options: full length of life (10 years, after which they die) in the health state to be valued or a shorter period in 'full health' (after which they die). The amount of time (months, years) to be spent in full health is varied until the respondent can no longer easily decide which option they prefer (the point of indifference), signalling the end of the exercise. The final utility value assigned to the health state being valued is given by the time spent in full health divided by the time spent in the health state (in this case 10 years). Thus, if the respondent was indifferent between living for 5 years in full health and living for 10 years in the health state being presented, the utility of that health state would be 5/10 = 0.50. The 'ping-pong' technique was employed to vary the amount of time in full health offered. The upper anchor employed in this study was 'full health' rather than 'perfect health' (as used in the measurement and valuation of health study[278]). The former is a more realistic and imaginable proposition. We presented the best pressure ulcer health state as the upper anchor, which states 'no bother' on all dimensions, as a representation of 'full health'. *Figure 32* shows a screenshot from the TTO survey.

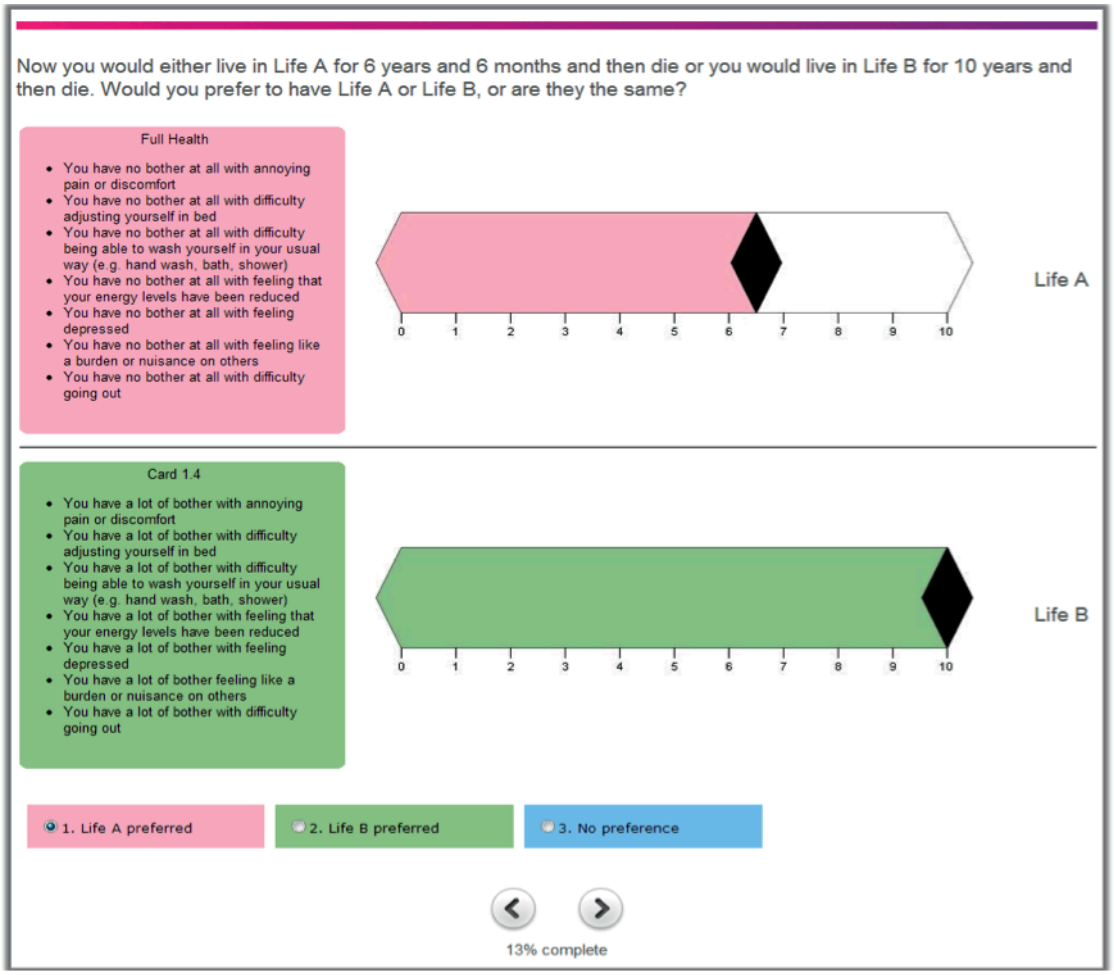

FIGURE 32 Screenshot of the TTO interview question. Reproduced with permission from Accent London, London, UK.

The formulation of the TTO for health states worse than death was that proposed by Torrance and colleagues:[302] if a respondent felt that they would rather die immediately than live for any amount of time in a given health state, the survey adapted to offer them a choice between immediate death and an amount of time in the health state being valued followed by the remaining time in full health. The longer the amount of time in full health required to compensate the poor health state, the worse the health state being valued is perceived. The utility value in this case is calculated as follows:

$$\text{time in full health}/(10 - \text{time in full health}). \quad (1)$$

In line with best practice, respondents were given information regarding pressure ulceration so that they based their interview responses on informed preferences. We chose not to include pictorial information on ulcers as it was difficult to identify pictures of pressure ulcers that corresponded with the full range of health states being valued.

The fourth section of the interview asked the interviewer to record how well he or she considered the respondent had understood the interview exercises, particularly the TTO questions. All interviews were carried out by experienced interviewers who had previous experience of using the computer-based TTO prop. In addition, the interviewers received additional training from one of the authors with substantial experience of undertaking health state valuation interviews. The responses to the ranking, scaling and TTO questions were automatically captured by the computer-based prop and communicated directly to the independent research company that carried out the interviews on behalf of the study investigators. The survey company was responsible for ensuring that recruitment was stratified such that the sample was representative (with consideration of gender, age, ethnicity and income) of the general population. The interviews lasted around 50 minutes. University ethical committee approval was gained before the survey began.

Analysis: modelling the health state valuations

The aim of the study was to construct a model that would predict the health state values for all 2187 states in the PUQOL-UI descriptive system from the measured health state data on the 52 health states in the estimation sample.

The standard model structure for a statistical inference health state valuation model is:

$$U_{ij} = g(\beta x_{ij} + \theta r_{ij}) + \varepsilon_{ij}, \quad (2)$$

where $i = 1,2,\ldots,n$ represents the individual health states of the descriptive system and $j = 1,2,\ldots,m$ represents the individual respondents to the survey. U_{ij} is the TTO valuation for health state i provided by respondent j. These valuations are modelled as a function of the sum of two items: x_{ij}, the vector of dummy variables for each response level on each domain of the descriptive system, and r_{ij}, a vector of interaction terms (which also depend on the levels of different domains). Finally, ε_{ij} is the error term. Aside from the function g, the only remaining parameters requiring estimation relate to the coefficients on the dummy variables (β) and on the interaction terms (θ).

Using the PUQOL-UI, level 1 ('no bother') as the baseline for each domain so that the vector x_i contains 14 dummy variables that indicate when each of the seven domains take one of the other two levels (level 2 'a little bother' and level 3 'a lot of bother'). The dummy variables take on a value of 1 when the health state being valued includes that domain at the specified level and a value of 0 otherwise. For a simple linear model, the intercept represents the value of full health and the value of any impaired health state is calculated by summing the coefficients of the 'on' dummy variables and subtracting this from 1.0.

Regression analysis of health state preference data has tended to estimate either ordinary least squares regression (assumes independent error terms have a zero mean and constant variance) or random-effects regression. The assumption for ordinary least squares regression means that the 1500 observations from 200 respondents are treated as though they were provided by 1500 distinct respondents. By contrast, the random-effects model acknowledges that the error term may not be independent of the respondent and thus separates out a within-respondent and between-respondent error term, that is:

$$\varepsilon_{ij} = u_j + e_{ij}, \tag{3}$$

where u_j is a respondent-specific variation and is random across individuals and e_{ij} is the residual error term for valuation i by individual j.

We report person-level main-effects models for the ordinary least squares and random-effects specification. The models are assessed according to the standard goodness of fit tests; the sign and logical ordering of parameters; and the predictive performance measured using the mean absolute error statistic, both within the estimation sample and for the validation sample.

Patient and public involvement

The research plan was presented to members of PURSUN UK at a meeting in January 2012. At that meeting the proposed valuation interviews were discussed in detail. PURSUN UK members expressed some concerns about the ability of the general public to imagine that they had a pressure ulcer (as required by the NICE[273] reference case TTO methods). This resulted in a dialogue about the need to balance the views of people with specific health-related experiences with those of the general public. Two members of the network volunteered to contribute to the patient information sheets, interview schedules and study protocols in more detail. Members of PURSUN UK who currently had or who had previously experienced a pressure ulcer were also involved in testing the revised PU-QOL instrument interviews.

As with the PU-QOL study, there was a need to balance the input of service users with accepted methods and guidelines in this field. Again, we found that the best way to manage this was to have an open and honest conversation with the group. Once it became apparent that more development work was needed (i.e. identifying a short-form version of the PU-QOL and additional changes to the question format), the input of PURSUN UK members proved invaluable. Members not only were able to try out and provide feedback on the new instrument, they also helped to recruit more participants to the study through their networks.

Results

Acceptability of the revised Pressure Ulcer Quality of Life instrument

Sixteen people were included in the interview testing of the revised PU-QOL instrument. All interviewees had previous experience of at least one pressure ulcer, lasting from 1 week up to 8 months, and three had a pressure ulcer at the time of the interview. The age of the sample ranged from 27 to 66 years (mean age 57 years) and 10 (62.5%) of the interviewees were male.

In general, the revised instrument was well received and the removal of the attribution aspect of the instrument caused no issues for comprehension or completion. However, some specific issues were raised about the instrument. For example, some respondents had difficulty deciding whether they had ‘a lot of bother’ or ‘no bother at all’ with carrying out some of the described activities either because they never did them or because someone else always did them for them. A few of the interviewees felt that the ordering of the different questionnaires was important. In cases in which both (attribution-free) generic and condition-specific measures with attribution were used, generic measures should be completed before condition-specific measures to avoid confusing respondents.

We were interested in whether or not the use of 'bothered' as a description was helpful and whether or not other terms such as 'affected' would be more suitable. The respondents either were indifferent or expressed positive approval of the current terminology.

Item selection

For the purposes of the item reduction analyses, the PU-QOL items were scored as follows: 'no bother' = 0, 'a little bother' = 1 and 'a lot of bother' = 2. For the Rasch analyses, when respondents reported that they 'have this problem but not because of their pressure sore', scores were recoded to '0'. This was to ensure that these respondents were not excluded from the analysis. However, as the Rasch analysis excludes extreme scores, a reduced sample was encountered regardless. For the traditional psychometric analyses (except where indicated), respondents' scores on these items were coded as 'missing'; this was to ensure that items were selected that reflected the greatest impact of pressure ulceration (without dilution of the general health considerations). As the current version of the PU-QOL instrument asked patients to think only about the impact of their pressure ulcer on aspects of their quality of life, there were significant floor effects in some domains (especially the non-pressure ulcer-specific domains), making item selection challenging.

Table 80 provides the correlations between the PU-QOL subscales and the global item, 'How would you rate your overall quality of life because of your pressure ulcer?' The lowest correlations were observed with the most obvious condition-specific scales: odour and exudate (leakage). The highest correlations were observed with the emotional well-being, participation and malaise/vitality scales. This finding suggests that the two most obvious pressure ulcer-specific dimensions have a weak impact on overall HRQoL whereas the emotional impact appears to be more significant. The implications for item selection were that we considered combining items from the odour and exudate domains to augment the response data and impact and that the inclusion of two items from the emotional well-being scale might be warranted. Given less weight in the selection process, but of interest nevertheless, were the correlations between the PU-QOL subscales and the SF-6D (*Table 81*), which exhibited a similar pattern as the correlations seen with global HRQoL.

Table 82 provides the item-by-item performance on the Rasch and traditional psychometric selection parameters. In general, few items suffered low factor loadings in factor analysis and none had ITCs below 0.4. Substantial floor effects were observed on items in several scales (i.e. exudate, odour, daily activities and self-consciousness). In the pressure ulcer-specific dimensions, it is possible that this was a result of the item issue not causing a lot of bother (hence scored '0').

In the more generic dimensions this was probably because the issue was not attributed to a pressure ulcer and was therefore scored '0'/coded missing – useable scores for the daily activities and mobility scales were very low for this reason. Notably, a number of items did not discriminate between ulcer categories (superficial vs. severe). All of the pain and sleep scale items, most mobility items, around half of the daily activities items and half of the vitality items failed to discriminate between groups. It is not clear why this would be the case although it is possible that some clinical features of superficial pressure ulcers may render the experience of them indistinguishable from the experience of severe pressure ulcers. Chapter 3 discusses why pain intensity may not be associated with ulcer category. For the mobility and daily activities scales, this finding may be an artefact of the low average scores because of the floor effects.

In general, most scales and items fit the Rasch model well, with few items exhibiting significant chi-square values, high residuals or DIF. However, there were exceptions, with the pain scale having three misfitting items, the emotional well-being scale incurring some DIF and the participation scale exhibiting a relatively high number of disordered thresholds.

TABLE 80 Correlations between a global quality of life item and the PU-QOL subscale scores

	PU-QOL subscales									
	Pain	Exudate	Odour	Sleep	Mobility	Daily activities	Malaise/vitality	Emotion	Self-consciousness	Participation
Correlation coefficient	0.386[a]	0.251[a]	0.177[a]	0.354[a]	0.414[b]	0.344[b]	0.543[a]	0.576[a]	0.493[a]	0.527[a]
p-value	0.000	0.000	0.009	0.000	0.011	0.017	0.000	0.000	0.000	0.000
n	206	216	217	166	37	48	135	133	176	75

a Correlation is significant at the 0.01 level (two-tailed).
b Correlation is significant at the 0.05 level (two-tailed).

TABLE 81 Correlations between the SF-6D and the PU-QOL subscale scores

	PU-QOL subscales									
	Pain	Exudate	Odour	Sleep	Mobility	Daily activities	Malaise/vitality	Emotion	Self-consciousness	Participation
Correlation coefficient	0.386[a]	0.251[a]	0.177[a]	0.354[a]	0.414[b]	0.344[b]	0.543[a]	0.576[a]	0.493[a]	0.527[a]
p-value	0.000	0.000	0.009	0.000	0.011	0.017	0.000	0.000	0.000	0.000
n	206	216	217	166	37	48	135	133	176	75

a Correlation is significant at the 0.01 level (two-tailed).
b Correlation is significant at the 0.05 level (two-tailed).

TABLE 82 Item-by-item performance on selection parameters

PU-QOL scale and items	Low PCF loading	Floor effect ≥ 50%[a]	Discriminate between PUs[b]	*R* – global item[c]	*R* – SF-6D[c]	Rasch misfit ($p < 0.01$)	Rasch residual ±2.5	Disordered threshold	DIF sex ($p < 0.01$)	DIF age ($p < 0.01$)
Pain	None						None	None	None	None
Feeling uncomfortable			N	0.318[d]	–0.295[d]	0.008				
Tenderness			N	0.277[d]	–0.238[d]					
Annoying pain or discomfort			N	0.373[d]	–0.269[d]					
Red raw		58	N	0.239[d]	–0.193[e]					
Stinging			N	0.294[d]	–0.173[e]					
Burning		61	N	0.188[d]	–0.178[e]					
Throbbing		55	N	0.290[d]	–0.255[d]					
Stabbing pains		68	N	0.211[d]	–0.302[d]					
Tingling		60	N	0.235[d]	–0.156[e]	0.000				
Exudate (leakage)	None					None	None		None	None
Weeping		71	N	0.191[d]	–0.151[e]					
Staining		73	Y	0.274[d]	–0.148					
Messy		78	Y	0.191[d]	–0.166[e]					
Causing dressing to come off		79	Y	0.183[d]	–0.185[e]			Y		
Running		84	Y	0.160[e]	–0.175[e]					
Sticky		78	Y	0.161[e]	–0.058					
Bleeding		83	Y	0.142[e]	–0.015					
Pus		89	N	0.089	–0.071			Y		

PU-QOL scale and items	Low PCF loading	Floor effect ≥ 50%[a]	Discriminate between PUs[b]	*R* – global item[c]	*R* – SF-6D[c]	Rasch misfit ($p < 0.01$)	Rasch residual ±2.5	Disordered threshold	DIF sex ($p < 0.01$)	DIF age ($p < 0.01$)
Odour	None						None	None		
An unpleasant smell		84	Y	0.171[e]	–0.116					
A stench or stink		90	Y	0.179[d]	–0.157[e]					
A pungent smell		89	Y	0.185[d]	–0.144					
A lingering smell		90	Y	0.179[d]	–0.149					
A sickening smell		91	N	0.171[e]	–0.087					
A putrid smell		91	N	0.186[d]	–0.176[e]					
Sleep	None							None	None	
Trouble finding a comfortable position			N	0.234[d]	–0.227[d]					
Having to sleep in one position (e.g. your back or side)			N	0.268[d]	–0.193[e]		2.64			
Not getting the amount of sleep that you needed		55	N	0.285[d]	–0.204[e]	0.001				
Interrupted sleep (e.g. restless sleep or being woken up during your sleep)		52	N	0.296[d]	–0.256[d]	0.009				
Being kept awake		61	N	0.248[d]	–0.239[d]					
Trouble falling asleep		61	N	0.243[d]	–0.254[d]					
Mobility	None								None	
Feeling that your walking was slowed down			Y	0.249[e]	–0.474[d]					
Feeling limited in your ability to walk			N	0.242[e]	–0.526[d]					
Difficulty adjusting yourself in bed			N	0.381[d]	–0.369[d]					
Difficulty turning or moving around in bed			N	0.410[d]	–0.318[d]					
Difficulty pushing up to a sitting position			N	0.370[d]	–0.441[d]					
Feeling limited in your ability to go up and down stairs		73	N	0.241	–0.223			Y		
Difficulty standing for long periods		57	Y	0.211	–0.538[e]			Y		

continued

TABLE 82 Item-by-item performance on selection parameters (*continued*)

PU-QOL scale and items	Low PCF loading	Floor effect ≥ 50%[a]	Discriminate between PUs[b]	*R* – global item[c]	*R* – SF-6D[c]	Rasch misfit ($p < 0.01$)	Rasch residual ±2.5	Disordered threshold	DIF sex ($p < 0.01$)	DIF age ($p < 0.01$)
Difficulty sitting (e.g. sitting up in bed or a chair)			N	0.327[d]	–0.219[e]					
Difficulty transferring (e.g. from a bed to a chair or to a car)			N	0.324[d]	–0.311[d]					
Daily activities	None					None	None			
Being able to wash yourself in your usual way (e.g. hand wash, bath, shower)		69	Y	0.287[d]	–0.334[d]					
Doing shopping		73	Y	0.259[e]	–0.566[d]			Y		Y
Doing your regular daily activities (e.g. work, volunteering, religious service, clubs, university)		71	Y	0.325[d]	–0.332[d]			Y		Y
Being able to go to the toilet		66	N	0.381[d]	–0.351[d]					
Doing jobs around the house (e.g. cooking, housework, DIY)		71	N	0.228	–0.384[d]			Y		
Getting dressed or undressed		65	N	0.327[d]	–0.283[d]					
Doing things that you enjoy (e.g. reading a book, watching a movie, using a computer)		81	N	0.367[d]	–0.366[d]					
Being emotionally close or affectionate with loved ones (e.g. able to cuddle, being intimate)		89	N	0.394[d]	–0.380[d]			Y		
Vitality/malaise	None							None	None	
Feeling that your appetite has reduced		76	N	0.340[d]	–0.437[d]					Y
Feeling that your energy levels have been reduced		55	Y	0.418[d]	–0.372[d]					
Feeling tired		51	Y	0.453[d]	–0.350[d]					
Feeling fatigued		52	N	0.467[d]	–0.335[d]					
Feeling unwell or poorly		69	N	0.533[d]	–0.351[d]					Y
Emotional well-being	None									
Feeling fed up			Y	0.406[d]	–0.323[d]				Y	

PU-QOL scale and items	Low PCF loading	Floor effect ≥ 50%[a]	Discriminate between PUs[b]	*R* – global item[c]	*R* – SF-6D[c]	Rasch misfit ($p < 0.01$)	Rasch residual ±2.5	Disordered threshold	DIF sex ($p < 0.01$)	DIF age ($p < 0.01$)
Feeling frustrated			Y	0.380[d]	–0.366[d]					
Feeling annoyed or irritated			Y	0.312[d]	–0.276[d]				Y	
Feeling miserable			Y	0.462[d]	–0.413[d]					
Feeling physically dependent on others			Y	0.479[d]	–0.396[d]					
Feeling concerned or worried		53	Y	0.419[d]	–0.257[d]				Y	
Feeling anxious			Y	0.461[d]	–0.417[d]				Y	
Feeling depressed		62	Y	0.428[d]	–0.358[d]					
Feeling like you have no control over your life because of your sore		60	Y	0.500[d]	–0.348[d]					
Feeling like a burden or nuisance to others		56	Y	0.458[d]	–0.460[d]				Y	
Feeling angry		70	Y	0.439[d]	–0.318[d]		Y			
Feeling like you were missing out		63	Y	0.426[d]	–0.422[d]					
Feeling lonely		73	Y	0.387[d]	–0.401[d]				Y	
Feeling cut off or isolated from others		75	Y	0.389[d]	–0.403[d]				Y	
Feeling that people avoided you or treated you differently now		91	Y	0.234[d]	–0.282[d]		Y			
Self-consciousness and appearance	None					None	None	None		None
Feeling helpless		60	Y	0.508[d]	–0.462[d]					
Lacking in confidence		69	Y	0.414[d]	–0.427[d]					
Feeling self-conscious		72	N	0.422[d]	–0.393[d]					
Feeling embarrassed		75	N	0.319[d]	–0.336[d]					
Feeling physically unattractive		83	N	0.312[d]	–0.366[d]					
Feeling uneasy being close to or around other people		85	Y	0.288[d]	–0.312[d]					
Feeling a lack of understanding from those close to you		84	Y	0.243[d]	–0.232[d]				Y	

continued

TABLE 82 Item-by-item performance on selection parameters (*continued*)

PU-QOL scale and items	Low PCF loading	Floor effect ≥ 50%[a]	Discriminate between PUs[b]	*R* – global item[c]	*R* – SF-6D[c]	Rasch misfit ($p < 0.01$)	Rasch residual ±2.5	Disordered threshold	DIF sex ($p < 0.01$)	DIF age ($p < 0.01$)
Social functioning/participation	None					None	None			
Being restricted to where you could go out			Y	0.476[d]	–0.446[d]			Y		
Being unable to get away for a holiday or make a trip at the weekend		62	Y	0.388[d]	–0.418[d]			Y		
Having to give up on hobbies or leisure activities		65	Y	0.403[d]	–0.434[d]			Y		Y
Difficulty going out			Y	0.430[d]	–0.583[d]					
Being restricted in how long you could stay out		58	Y	0.356[d]	–0.411[d]			Y		
Having to plan going out around pressure sore care		79	Y	0.305[d]	–0.303[d]			Y		
The amount of time involved in caring for your sore		79	Y	0.211[d]	–0.302[d]			Y		
Being unable to participate in family gatherings or activities		75	Y	0.440[d]	–0.385[d]					
Difficulty meeting up or seeing family and/or friends		73	Y	0.404[d]	–0.406[d]			Y		

N, no; PCF, principal components factor; PU, pressure ulcer; *R*, correlation; Y, yes.
a ≥ 50% of respondents obtain the lowest possible score.
b *t*-test for superficial vs. severe pressure ulcer.
c Spearman correlation.
d Correlation is significant at the 0.01 level (two-tailed).
e Correlation is significant at the 0.05 level (two-tailed).

The items selected based on qualitative and quantitative assessments are included in *Table 83* along with the justification for selection. Two items were included from the emotional dimension as the analysis indicated that this was one of the most significant impacts of pressure ulcers. Given that these 11 candidate items would result in a possible 177,147 health states (3^{11}) for valuation, we explored ways to reduce or combine items further. We combined the exudate and odour item into one joint item; however, further item reduction was indicated (*Table 84*).

TABLE 83 Candidate items for inclusion in the PUQOL-UI

PUQOL-UI item number	PU-QOL scale/dimension	Original PU-QOL item number and description	Justification for item inclusion
1	Pain	3. Annoying pain or discomfort	• EQ-5D dimension • Clearest pain item • Low floor effect • Pain item with highest correlation with global quality of life
2	Exudate	10. Weeping from your pressure ulcer	• PU-specific dimension • Lowest floor effect • Second-highest correlation with global quality of life
3	Odour	18. An unpleasant smell from your pressure ulcer	• PU-specific dimension • Lowest floor effect • Discriminates between PU categories
4	Sleep	27. Interrupted sleep (e.g. restless sleep or being woken up during your sleep)	• Only moderate floor effect • Not in the EQ-5D but likely an important domain and captures the idea that pain and positioning limitations from a PU interfere with sleep • Highest correlation with global quality of life
5	Mobility	31. Difficulty adjusting yourself in bed	• Preferred over walking items as many of this group will be wheelchair users • Smallest floor effect
6	Daily activities/ self-care	39. Difficulty being able to wash yourself in your usual way (e.g. hand wash, bath, shower)	• EQ-5D dimension • Captures the idea that pressure sore and bandages may interfere with self-care • Only moderate floor effect • Discriminates between PU categories
7	Malaise/vitality	49. Feeling that your energy levels have been reduced	• Moderate floor effect • Discriminates between PU categories
8	Emotional well-being	60. Feeling depressed	• EQ-5D dimension • Discriminates between PU categories • High correlation with global quality of life and SF-6D
9	Emotional well-being	62. Feeling like a burden or nuisance on others	• EQ-5D dimension • Discriminates well between PU categories • Captures emotion and also level of care required, which should be a function of severity • Two emotion items may be justified as this scale has the highest overall correlation with global quality of life
10	Self-consciousness	69. Lacking in confidence	• Second lowest floor effect • Discriminates between PU categories • Third-highest correlation with global quality of life
11	Participation	78. Difficulty going out	• Lowest floor effect • Discriminates between PU categories • Highest correlation with SF-6D

PU, pressure ulcer.

TABLE 84 Further item reduction

Dimension	Item	Justification for removal
Exudate and odour	Weeping or an unpleasant smell from your pressure sore (combined item)	Although this appears to be the most 'condition specific' of the dimensions, the results indicate that the issue may have a relatively limited impact on quality of life. Weeping and odour items had high floor effects (71% and 84% respectively) and low correlations with the overall PU-QOL (0.191 and 0.171 respectively). These correlations were the lowest observed with global pressure ulcer quality of life, even when combined into one variable
Sleep	Interrupted sleep (e.g. restless sleep or being woken up during your sleep)	The item did not discriminate between ulcer categories and had a low correlation with global pressure ulcer quality of life. It is likely that a large proportion of the impact captured in the item will also be captured by the item relating to vitality
Self-consciousness	Lacking in confidence	It is likely that the impact of this item is captured by others. The items on depression and being a nuisance were combined into one variable and correlated with this item to determine the extent to which it captures unique impact. As the correlation was relatively high ($r = 0.59$) it was concluded that this item provides little additional information and should be removed

Thus, after the second iteration of item reduction, a final PUQOL-UI measure consisting of seven items was settled on [available from the University of Leeds CTRU website: http://medhealth.leeds.ac.uk/puqol-ques (accessed July 2015). Despite the level of item reduction, the Rasch item map suggests that the seven remaining items span a relatively wide range on the latent trait continuum (*Figure 33*). A non-trivial level of floor effect remains but this is likely to be related to the response data being attributable only. Despite the loss of the odour and exudate items, the PUQOL-UI retains domains that are highly pertinent for this group, capturing moving in bed, energy levels and the sense of being a burden on others. This is in addition to important generic health impacts such as pain and self-care.

Health state valuation survey

In total, 200 valuation interviews were successfully completed in June 2013. Of the sample, 54% of respondents were female, 51% were married or in a civil partnership and 67% were in some form of employment or full-time education. Over half of the sample (56%) had completed secondary education and 38.5% had completed post-secondary education. In terms of self-rated health, 82.5% reported their health as 'good' or 'very good' and only 1.5% reported their health as 'very poor'. *Table 85* reports the mean, minimum and maximum values and the number of observations for each of the health states in the estimation sample. *Figure 34* presents a histogram of the utility values.

Table 86 reports the parameter coefficients for the main-effects ordinary least squares and random-effects models, as well as the significance values for each parameter. It also reports the adjusted R^2, the mean absolute error for each model and the *t*-test for the expected value of the errors being significantly different from zero. Note that the parameters for the models are identical at three decimal places, with some changes in the significance of some of the coefficients. It is also worth noting that we fitted terms for interactions between level 3 on each domain. Although the resulting models produced significant coefficients on some of the interaction dummies – notably the burden and depression interaction – the coefficients on a number of main effects became non-significant and lost their logical ordering. Therefore, we have not reported these models in detail.

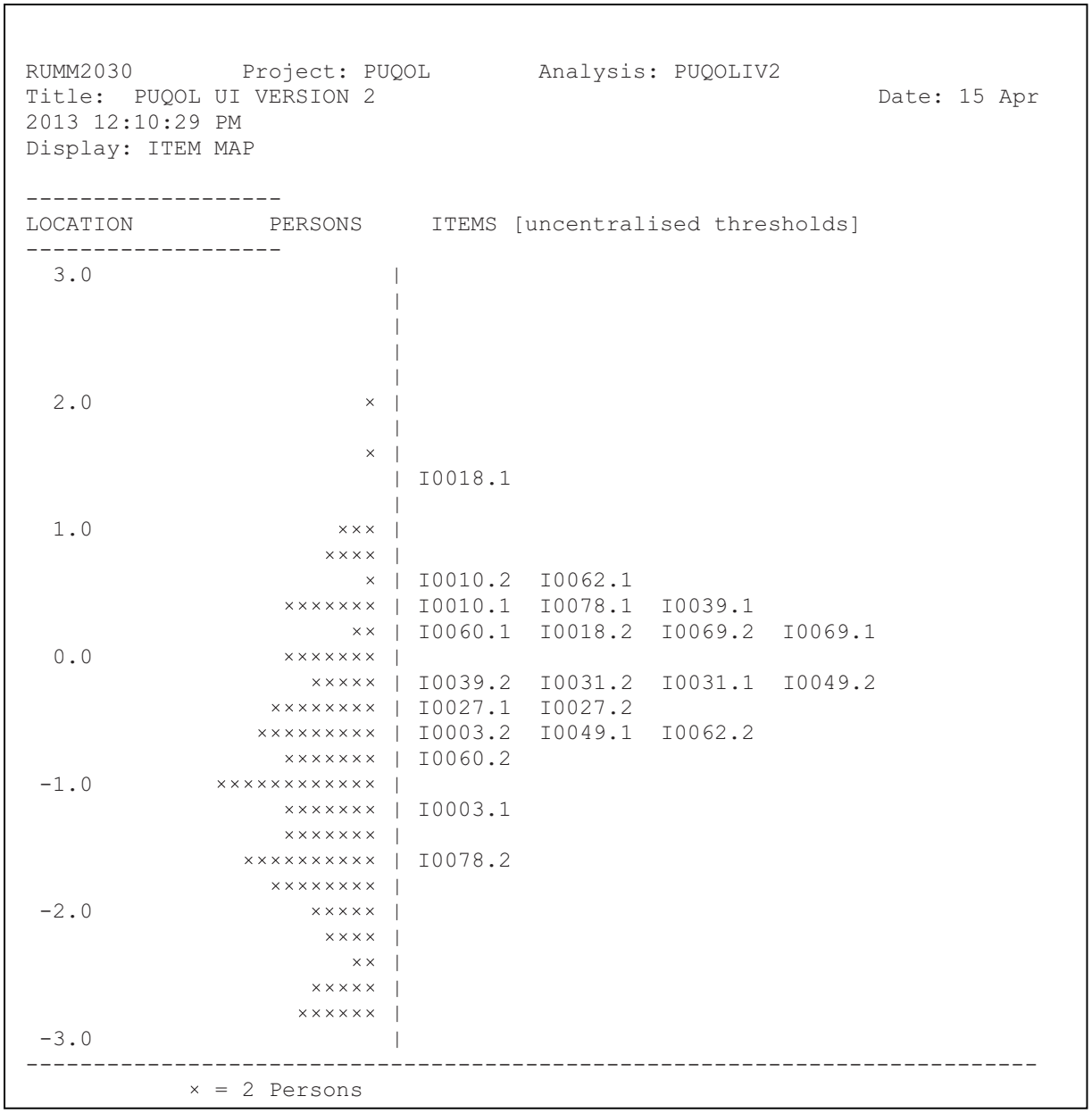

FIGURE 33 Item map for the final PUQOL-UI.

TABLE 85 Summary statistics for the health state values in the estimation sample

State	Mean	Minimum	Maximum	*n*
1111113	0.829	0.28	1	25
1111131	0.866	0.48	1	26
1111222	0.871	0.1	1	25
1111311	0.871	0.48	1	25
1112131	0.718	–0.6	1	25
1112313	0.745	0.28	1	25
1113111	0.829	–0.01	1	25
1121133	0.646	0	1	24
1123321	0.870	0.3	1	25
1131111	0.775	0	1	49
1131211	0.793	0	1	25
1133112	0.691	0.28	1	25
1211311	0.798	0	1	25
1212113	0.742	–0.38	1	24
1221111	0.860	0	1	25
1223212	0.761	0	1	25
1311111	0.876	0	1	25
1311132	0.781	0.28	1	25
1312221	0.830	0.33	1	25
1331323	0.735	0	1	25
1333111	0.727	0	1	24
1333333	0.402	–0.74	1	25
2121331	0.686	0	1	25
2122122	0.836	0.38	1	25
2122222	0.808	0.28	1	26
2131113	0.784	–0.38	1	25
2132211	0.747	–0.48	1	25
2211231	0.806	0.38	1	25
2213123	0.728	0.28	1	25
2222122	0.727	0	1	26
2222222	0.877	0.43	1	25
2311112	0.730	–0.9	1	25
2313311	0.638	–0.21	1	25
3111111	0.766	0.28	1	25
3111121	0.700	0	1	25
3111312	0.707	0.18	1	25
3113111	0.724	0	1	25

TABLE 85 Summary statistics for the health state values in the estimation sample (*continued*)

State	Mean	Minimum	Maximum	*n*
3113233	0.510	–0.21	1	24
3133333	0.358	–0.9	1	25
3231121	0.672	0	1	26
3232332	0.508	–0.38	1	26
3232333	0.444	–0.9	0.93	24
3313333	0.367	–0.9	1	24
3321213	0.613	0.28	1	25
3322111	0.667	0	1	25
3331333	0.353	–0.9	1	25
3332332	0.506	–0.6	1	26
3333133	0.469	–0.9	1	25
3333313	0.436	–0.9	1	51
3333331	0.317	–0.9	0.9	25
3333333	0.375	–0.9	1	200

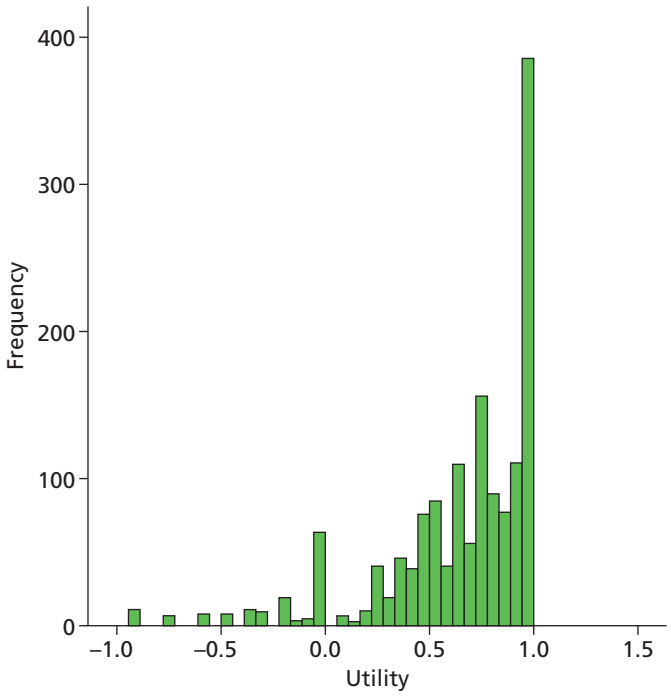

FIGURE 34 Histogram of utilities in the model estimation data set. Mean 0.65, SD 0.376, $n = 1500$.

TABLE 86 Main effects ordinary least squares and random-effects regression models

	OLS regression model		RE regression model	
Dimension and level	β (SE)	Significance	β (SE)	Significance
Constant	1.00		1.00	
Pain 2	–0.056 (0.027)	0.036	–0.056 (0.024)	0.018
Pain 3	–0.138 (0.023)	0.000	–0.138 (0.018)	0.000
Mobility/adjusting self in bed 2	–0.045 (0.025)	0.075	–0.045 (0.022)	0.038
Mobility/adjusting self in bed 3	–0.074 (0.022)	0.001	–0.074 (0.022)	0.001
Self-care 2	–0.047 (0.027)	0.075	–0.047 (0.020)	0.017
Self-care 3	–0.106 (0.022)	0.000	–0.106 (0.021)	0.000
Energy 2	–0.049 (0.025)	0.055	–0.049 (0.021)	0.020
Energy 3	–0.100 (0.022)	0.000	–0.100 (0.019)	0.000
Depression 2	–0.030 (0.026)	0.243	–0.030 (0.021)	0.152
Depression 3	–0.072 (0.023)	0.002	–0.072 (0.020)	0.000
Burden 2	–0.006 (0.026)	0.821	–0.006 (0.021)	0.779
Burden 3	–0.095 (0.023)	0.000	–0.095 (0.020)	0.000
Social participation 2	–0.038 (0.026)	0.139	–0.038 (0.020)	0.050
Social participation 3	–0.093 (0.023)	0.000	–0.093 (0.022)	0.000
n	1500		1500	
Mean absolute error				
Estimation	0.064		0.064	
Validation	0.081		0.081	
Ljung–Box test	23.49	0.432	23.49	0.432

OLS, ordinary least squares; RE, random effects; SE, standard error.

The mean absolute error records how far away the mean predicted value of a state (using the regression results) is from the mean observed value of a state. The lower the mean absolute error, the better the fit for that state. In general, the more states are within a specified distance from the observed values, the better the fit of the model. *Figure 35* plots the proportion of all estimated states ($n = 51$) that have mean absolute errors below a given tolerance, as we vary that tolerance. As the parameters for both the ordinary least squares and the random-effects models are nearly identical, the mean absolute error curves are indistinguishable and so we have not plotted these separately. *Figure 36* plots the observed and predicted health state values and prediction errors for the states in the estimation sample. *Figure 37* does the same for eight states in the validation data set. It also reports the mean absolute error for the predictions of the validation state mean utilities. *Table 87* reports the summary statistics for the health states in the validation sample.

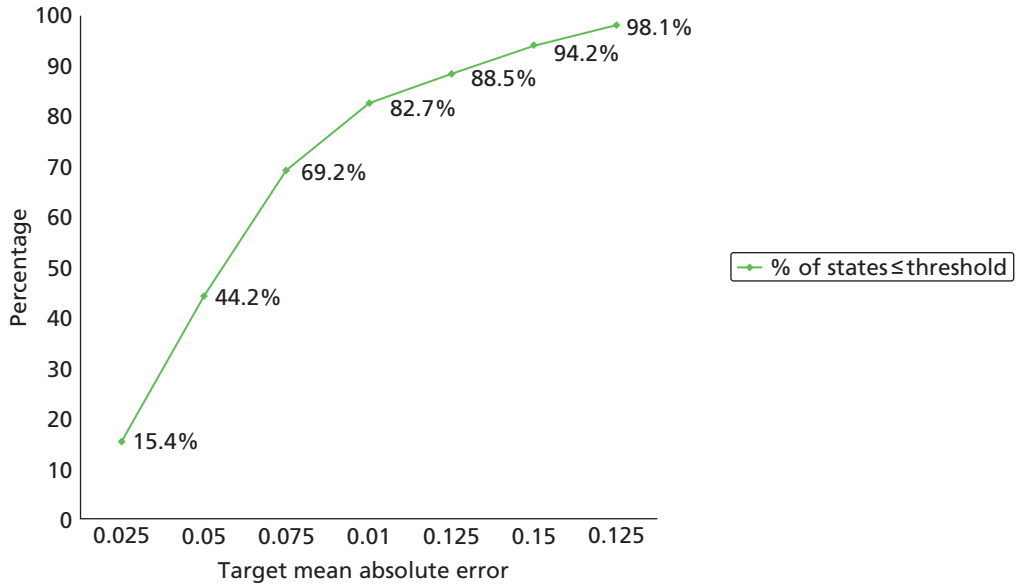

FIGURE 35 Mean absolute error curve. Proportion of predictions with target mean absolute error range.

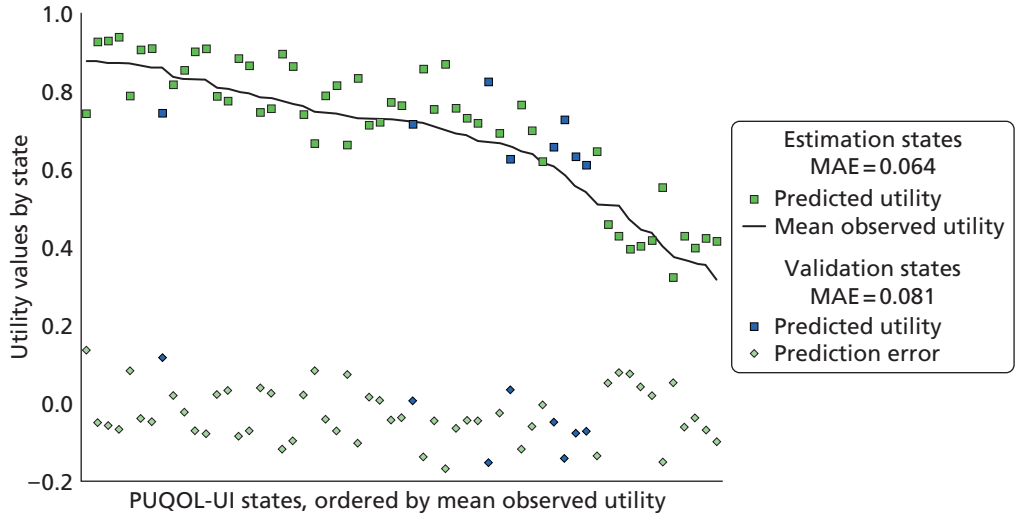

FIGURE 36 Observed and predicted health state utilities with prediction errors. MAE, mean absolute error.

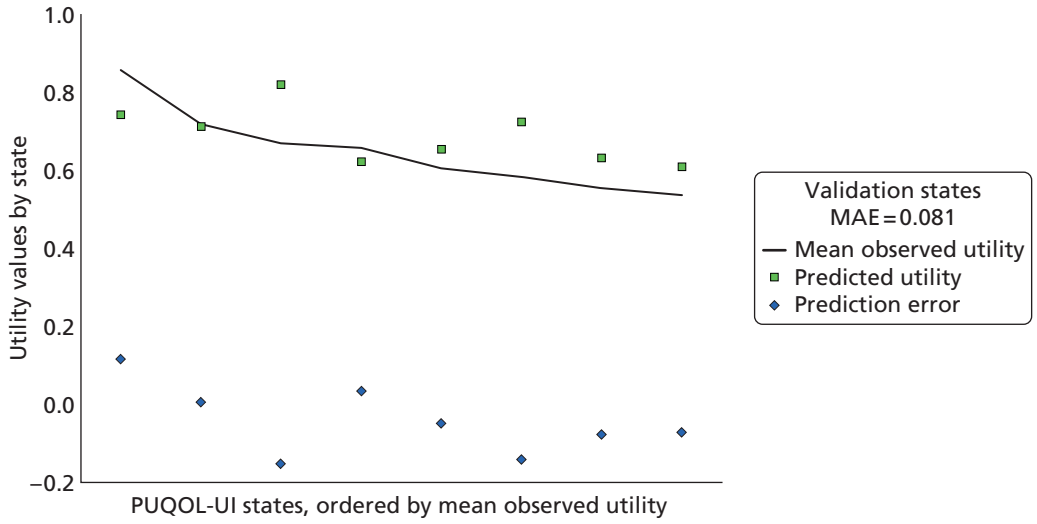

FIGURE 37 Mean and predicted health state utilities and errors: validation data set. MAE, mean absolute error.

TABLE 87 Summary statistics for health states in the validation data set

State	Mean	Minimum	Maximum	*n*
1212232	0.86	0.82	1.00	25
1333312	0.54	0.47	0.82	25
2112323	0.67	0.50	0.93	25
2232211	0.72	0.63	0.95	24
3122312	0.61	0.42	0.88	26
3133221	0.56	0.47	0.72	25
3213113	0.66	0.42	0.88	25
3311222	0.58	0.47	0.72	25

Validation study

The analysis for identifying the PU-QOL item subset to construct the valuation health states was based on data generated using the original 'pressure ulcer-attributable' wording of the measure, which does not reflect the 'attribution-free' format of the PUQOL-UI. Although there are no empirical studies in this space to confirm this, it is possible that, when the attribution is removed, the performance of the PUQOL-UI items may change. The validation study (study B) aimed to generate a data set using the revised (attribution-free) PU-QOL instrument to enable item analysis, to identify whether the performance of the selected items is adversely affected by the removal of attribution. The data set would also allow preliminary validation of the PUQOL-UI (see *Appendix 52* for the study protocol).

Aim and objectives

The aim of the validation study was to validate the PUQOL-UI (in terms of item selection and psychometric performance). Specific objectives were to:

1. collect data on the revised attribution-free PU-QOL
2. verify the item selection for the PUQOL-UI using attribution-free PU-QOL data
3. conduct a preliminary validation of the PUQOL-UI.

Methods

Study design

A sample of NHS patients with pressure ulcers completed the researcher-administered revised PU-QOL instrument in hospital. The sample size was dependent on that required to obtain robust estimates from the Rasch analysis. Linacre[238] proposed that for most purposes a sample size of 100 (range 64–144) will provide 95% confidence of item calibration within ±0.5 logits. In this study we aimed for 95% confidence and therefore a sample of 100 patients was recruited across multiple sites between July and November 2013.

Data collection

Patients who consented to participate (see *Appendix 53* for the patient information sheet and consent form) completed the revised (attribution-free) 82-item PU-QOL and the EQ-5D-3L (see *Appendix 54* for the questionnaire booklet). These were interviewer administered by research nurses in the inpatient setting. A set of sociodemographic and pressure ulcer-related questions was also completed. The latter included clinical grading of the pressure ulcer by the nurse. In cases in which the patient had more than one pressure ulcer the nurse returned the highest category of any of the pressure ulcers present. Ethical committee approval was gained for the study (National Research Ethics Service Committee North East – York; reference number 13/NE/0152).

Item selection analyses

The item analysis described in *Valuation study: general population survey, Analysis* was conducted again although on this occasion emphasis was on evaluating the items that had been selected for the PUQOL-UI rather than item selection. In addition, correlations were conducted with the EQ-5D rather than with the SF-6D. The internal consistency of the PUQOL-UI was evaluated as was criterion validity (through correlations with the EQ-5D).

Pressure Ulcer Quality of Life – Utility Index validation

The PUQOL-UI was scored employing the random-effects algorithm and the following analyses were conducted:

- examination of utility score descriptives and distribution
- assessment of criterion validity through correlations with the EQ-5D
- assessment of the ability of the PUQOL-UI to discriminate between pressure ulcer severity and general health groups.

Analyses were conducted in RUMM2030 and Stata version 12 (StataCorp LP, College Station, TX, USA).

Results

Sample

In total, 100 patients with a current pressure ulcer participated in the study, including 52 patients from acute hospital NHS settings and 48 from community hospital, residential and home care settings (see *Appendix 1* for recruitment by participating centre). The sample was well balanced in terms of gender, age, educational status and pressure ulcer category. The sample was also similar for these attributes to that which provided the data for the item selection analysis, thus ensuring that comparison is possible. The sample details are provided in *Table 88*.

TABLE 88 Validation sample characteristics

Characteristic	*n*
Gender	
Male	51
Female	49
Age (years)	
Mean (SD)	77.16 (15.33)
Range	22.67–101.67
Ethnicity	
White	98
Black or black British	2
Highest level of education	
University or college or equivalent	13
Intermediate between secondary level and university	23
Secondary school	55
Primary school (or less)	9
Wheelchair user	
Yes	50
No	50
Pressure ulcer duration (months)	
Mean (SD)	9.91 (17.3)
Range	0.23–96.0
More than one pressure ulcer	
Yes	14
No	86
Pressure ulcer category	
1	14
2	37
3	21
4	24
Missing	4
Self-rated pressure ulcer severity	
Very severe	11
Severe	19
Moderate	36
Mild	18
Very mild	13
Missing	3

Item analyses

A summary of the item analyses is included in *Table 89*. The analysis did not identify any significant problems with the seven items selected for the PUQOL-UI that would warrant their exclusion from the measure. None of the PUQOL-UI items misfit the Rasch model, had low factor loadings or low ITCs. The items showed minimal floor effects and all but one of the items ('Difficulty going out') correlated significantly with the EQ-5D. Correlations with the global health item were generally lower although this likely relates to the number of data points available. Only one of the selected items discriminated between pressure ulcer category groups. However, this was the case for all of the items in the pain, sleep, mobility and malaise/vitality dimensions when all items were analysed. A number of items in the exudate and odour dimensions discriminated between pressure ulcer groups. However, as in the initial item selection, high floor effects were observed in these dimensions (range 68–94% in the exudate and 87–97% in the odour dimensions) as well as low correlations with global health and as such their exclusion from the PUQOL-UI is vindicated. Only one item in the daily activities and emotional well-being dimensions and two items in the self-esteem scales discriminated between pressure ulcer category groups. These may have been candidates for inclusion in the utility index; however, it is possible, given the number of statistical tests conducted, that the significant differences are spurious.

Overall, the item analysis based on the attribution-free PU-QOL did not identify any performance issues with the PUQOL-UI items nor an alternative configuration of the measure that was clearly preferable to the one that was chosen. Therefore, the PUQOL-UI format and item make-up is confirmed as an acceptable and valid basis of pressure ulcer health states for valuation. Although of secondary importance, the scale properties were also found to be adequate with a reasonable level of item inter-relatedness (Cronbach's alpha = 0.74), with good fit to the Rasch model with no individual item misfit.

TABLE 89 Item selection analysis for the PUQOL-UI

PU-QOL scale and items	Low PCF loading[a]	Floor effect ≥ 50%[b]	ITC	Discriminate between PUs[c]	*R* – global item	*R* – EQ-5D
Pain						
Annoying pain or discomfort			0.710	N	0.289[d]	0.313[d]
Mobility						
Difficulty adjusting yourself in bed			0.764	N	0.224[e]	0.339[d]
Daily activities						
Being able to wash yourself in your usual way (e.g. hand wash, bath, shower)			0.741	N	0.170	0.357[d]
Vitality/malaise						
Feeling that your energy levels have been reduced			0.795	N	0.339[d]	0.250[e]
Emotional well-being						
Feeling depressed		55.10	0.778	N	0.328[d]	0.411[d]
Feeling like a burden or nuisance to others			0.743	N	0.166	0.368[d]
Social functioning/participation						
Difficulty going out			0.827	Y	0.128	0.138

N, no; PCF, principal components factor; PU, pressure ulcer; *R*, correlation; Y, yes.
a All PCF loadings < 0.2.
b ≥ 50% of respondents obtain the lowest possible score.
c *t*-test for superficial vs. severe PU.
d Correlation is significant at the 0.05 level (two-tailed).
e Correlation is significant at the 0.01 level (two-tailed).

Pressure Ulcer Quality of Life – Utility Index validation

The PUQOL-UI exhibited a greater number of missing values than the EQ-5D. This might in part be explained by the greater number of items in the full PU-QOL and associated respondent fatigue, which may be not be an issue when the seven-item PUQOL-UI is completed. The range of observed PUQOL-UI scores (*Table 90*) were close to the possible range of the measure (0.322–1) in this sample but with no evidence of a floor or ceiling effect that might jeopardise the responsiveness of the measure. The PUQOL-UI scores were significantly higher than the EQ-5D scores. Correlations with the EQ-5D were moderate ($r = 0.54$; $p < 0.001$; $n = 82$) indicating a moderate level of shared variance.

Neither the PUQOL-UI nor the EQ-5D were able to distinguish (to a statistically significant degree) between patients grouped according to pressure ulcer category (categories 1 and 2 vs. categories 3 and 4). However, the PUQOL-UI was able to discriminate between patients grouped according to number of pressure ulcers, self-reported severity of ulcer and self-reported health. The discriminatory power of the PUQOL-UI appeared to be greater than that of the EQ-5D, which could not discriminate between self-rated general health groups or by number of current pressure ulcers. This suggests that the new utility index is a valid measure of health state preferences in people with pressure ulcers.

TABLE 90 Descriptive scores and tests of validity for the utility measures

	PUQOL-UI	EQ-5D
n	84	94
Mean (SD)	0.70 (0.18)	0.19 (0.37)
Range	0.32 to 0.99	–0.59 to 0.85
Pressure ulcer category, mean (SD)		
Superficial (categories 1–2)	0.72 (0.17)	0.24 (0.36)
Severe (categories 3–4)	0.67 (0.19)	0.15 (0.38)
p-value[a]	0.17	0.28
Self-rated pressure ulcer severity, mean (SD)		
Mild	0.78 (0.16)	0.29 (0.36)
Moderate	0.72 (0.17)	0.25 (0.34)
Severe	0.58 (0.17)	0.04 (0.40)
p-value[b]	< 0.001	0.023
Self-rated general health, mean (SD)		
Good	0.75 (0.18)	0.23 (0.40)
Moderate	0.72 (0.16)	0.26 (0.35)
Poor	0.58 (0.18)	0.03 (0.40)
p-value	0.006	0.073
Number of current pressure ulcers, mean (SD)		
1	0.72 (0.18)	0.21 (0.38)
> 1	0.58 (0.18)	0.07 (0.30)
p-value	0.012	0.206

a *t*-test.
b ANOVA.

Discussion

The PU-QOL instrument is a comprehensive measure of HRQoL that captures a wide range of clinical, personal, social and broader role effects of pressure ulcers. Having been developed with a view to utilisation in both the clinical and the population research setting, it asks respondents to focus on the component of their health that is attributable to their pressure ulcer. Both the scope of the instrument and the attribution form of the questions created challenges to the development of a short-form preference-based version of the instrument that could be used in the economic evaluation of pressure ulcer prevention and treatment technologies. The challenge from the instrument attribution would not have arisen had a non-attribution format been employed. However, the team involved in the development of the PU-QOL had specified a priori a desire to create a measure that captured only pressure ulcer-specific impact and that because of the prevalence of significant comorbidities in this group it was necessary for the instrument to enquire only about pressure ulcer impact.[221]

The challenge represented by the scope of the PU-QOL instrument is one common to many short-form development projects and, in line with other researchers, we used psychometric assessment and Rasch analysis to identify a reduced set of domains and levels that were strongly related to measured global health. The short form consists of seven domains and is thus within the accepted scope for health state valuation – based on the psychological literature which reports that people can process between five and nine pieces of information in arriving at a decision. Although a number of the more clinical domains of the PU-QOL were dropped from the short version, this was based on analysis of the data rather than on any prior judgement on the researchers' part.

The concern with the attribution form of the PU-QOL related to the feasibility of respondents parsing the value of pain, depression, burden, etc. attributable to their pressure ulcer if they had comorbidities that also impacted on these domains of HRQoL. Therefore, we undertook a small interview study of people with pressure ulcers and asked them to complete the PU-QOL questions without the attribution format. Respondents had no difficulty completing the revised question format and did not report problems with its meaning or relevance in the absence of the 'attribution' question format. On this basis we moved forward with the development of the short-form instrument – the PUQOL-UI.

Having decided to proceed with the valuation of the PUQOL-UI we had to consider whether to obtain patient or general population values for the health states it described. Although it is increasingly accepted that the description of the impact of a condition on an individual's health should come from relevant service users, it is still recommended that, when valuations are intended to inform population health-care resource allocation decisions, these should come from the general population rather than from the patients. Therefore, we chose the general population as the population to sample for the health state valuation survey. It would be interesting to know the location and the magnitude of any differences between patient and general population values for health states described by the PUQOL-UI. However, the additional valuation surveys necessary to address this question were beyond the resources available to this study.

In line with recommendations from NICE,[273] we chose to use the TTO method for obtaining health state values, using props and timelines based on the UK measurement and valuation of health study,[277] which produced the algorithm for the EQ-5D. Like the measurement and valuation of health study,[277] we undertook an interviewer-administered survey to enable us to have more confidence in the quality of the data obtained, both through interviewer training and reporting back on interviewee comprehension.

The recommended utility algorithm is, perhaps surprisingly, a simple linear additive model. However, this was the model that best fit the data and produced acceptable predictive performance in both the estimation and the validation data set. Additional work to assess whether or not more sophisticated model specifications, such as generalised linear models and two-part models, produce better-performing

algorithms could be undertaken. However, the random-effects main-effects regression model performs acceptably and is comparable in many ways with widely used utility algorithms such as the SF-6D.

Additional efforts were expended in checking that the item selection process had been valid. This was perhaps not critical as the psychometric properties of a utility measure can be established only ex post when the utility weights are available and as item selection based on unweighted item responses provides only an idea of which items are most suitable. However, the item analysis conducted in the validation study did verify that the items selected for inclusion in the PUQOL-UI were a good representation of the long form of the measure and confirmed the validity of the 'attribution-free' format. Psychometric analyses also suggested that the PUQOL-UI has adequate levels of discriminatory power and may have greater power than the EQ-5D. Further work is required to compare the performance of the EQ-5D and that of the PUQOL-UI to determine whether or not the condition-specific measure indeed confers measurement benefits and also to determine the responsiveness of the PUQOL-UI over time. PUQOL-UI values were much higher than those observed on the EQ-5D. It is likely that this is an artefact of the much greater range on the EQ-5D and the lower values drawing the mean lower. The EQ-5D has a much lower bound than the PUQOL-UI and this may be because it describes more severe health states (e.g. 'I am unable to wash or dress myself' in the EQ-5D vs. 'Having a lot of bother washing yourself in the usual way' in the PUQOL-UI).

Conclusions

The development of a condition-specific, preference-based measure for use in economic evaluations of pressure ulcer preventative and treatment interventions has been a success. A brief measure – the PUQOL-UI – has been identified and valued using general population TTO tasks. The subsequent modelling identified a robust algorithm that delivers the utility values necessary for cost–utility analysis. The PUQOL-UI complements the PU-QOL instrument as the latter delivers a comprehensive assessment of patient quality of life; investigators should consider employing both instruments in future pressure ulcer studies. Further work is necessary to establish the responsiveness of the PUQOL-UI, especially compared with generic preference-based measures. Future methodological work should explore the impact of condition attribution in health measurement and valuation, especially when comorbidities exist in the population of interest.

The final PUQOL-UI instrument and the associated utility scoring algorithm syntax (in SPSS and Stata) are available from http://medhealth.leeds.ac.uk/puqol-ques (accessed July 2015).

Chapter 8 Conclusions, wider impacts and recommendations

Summary

The PURPOSE clinical and academic partnership has been successful in developing and delivering a world-leading applied health research programme in the field of pressure ulcer prevention. The PURPOSE programme has addressed fundamental issues identified by patients and provides the foundation for the development of evidence-based, patient-centred practice in the field and a future clinical trials portfolio.

Our pain prevalence study has indicated that hospital and community patients experience both pressure area-related and pressure ulcer pain and results from our cohort study indicate that pain is independently predictive of category 2 (and above) pressure ulcer development. This is the first cohort study to have explored pain as a risk factor and supports patient reports from previous qualitative work[9] that pain had preceded the clinical presentation of their pressure ulcer.

Similarly, our work on severe pressure ulcers is the first study to have investigated different explanations for their development, linking the literature on pressure ulcer development to the broader literature on patient safety, the management of clinical risks and the investigation of reportable incidents. There is an unhelpful divide between those such as Francis,[93] who stress the importance of organisational and cultural explanations for adverse events, and the bulk of the academic literature, which continues to focus on errors made by individual clinicians.[112] Our findings show that it is possible to reconcile these perspectives: severe pressure ulcers are more likely to occur where individuals fail to respond to clear signs, when there are wider problems with the contexts in which they are working. This has practical implications for the conduct of root cause analyses in the NHS. Analyses currently focus on identifying specific decisions or actions and encourage teams to attach blame to individuals. Broader organisational and cultural considerations should be included in root cause analyses.

The pressure ulcer risk factor systematic review highlighted the need for high-quality risk factor research in the field, common standards for the definition of key risk factors and improved data sets underpinned by a conceptual model for the development and testing of prediction models. We therefore developed a risk factor Minimum Data Set and used this to form the basis of a Risk Assessment Framework, the PURPOSE-T, using consensus methods underpinned by the best available evidence. Decisions incorporated the views of service users. The risk assessment work incorporated key findings from the pain and severe pressure ulcer work packages, namely the inclusion of pain in the Risk Assessment Framework and designing the framework to distinguish between primary prevention and secondary prevention/treatment decision pathways.

The development of PROs for the assessment of quality of life and health utilities provide tools for use in future effectiveness research and patient-directed treatment plans that are both evidence based and focused on important outcomes for patients.

Related themes: practice implementation

A number of related themes have emerged from the results of the work:

(a) Patient's reports of pain preceding pressure ulcer development are dismissed by nurses (quality of life work package).
(b) Patients reported that pain is their most distressing symptom, but little priority was given to pain, which is not systematically assessed or treated effectively (quality of life work package).
(c) Pain is a common problem and is reported by patients with pressure ulcers but also by a small number of patients without pressure ulcers on 'at-risk' skin sites (pain work package).
(d) The presence of pain is a predictor of subsequent category 2 pressure ulcer development (pain work package).
(e) Severe pressure ulcers were more likely to develop when:

- nurses failed to listen to patients/carers
- nurses failed to recognise deterioration in condition or acknowledge the presence of an existing pressure ulcer (severe work package).

(f) Current risk assessment does not make a distinction between those patients who have no pressure ulcers but who are at risk and require primary prevention and those patients who have an existing pressure ulcer or scarring from a previous pressure ulcer who require secondary prevention and treatment (risk assessment work package).
(g) Severe pressure ulcers developed when there was no response or escalation of care despite clear signs that a pressure ulcer was developing (blanching redness to category 1) or deteriorating (e.g. from category 1 to category 2) (severe work package).
(h) Severe pressure ulcers developed in situations in which effective pressure relief was difficult to achieve, for example because of a patient's capacity to understand and respond to advice or because of physical limitations such as contractures. The problems were not, though, attributable solely to the complexity of the problems. Severe pressure ulcers developed in cultural contexts in which some staff were prepared to blame patients for what had happened.
(i) Skin status is a key risk factor for pressure ulcer development, including alterations to intact skin, and critically the presence of a category 1 pressure ulcer is predictive of category 2 and above pressure ulcer development (pain and risk work packages).
(j) Service provision, particularly in the community setting, is fragmented and not patient focused. This was evident in the prevention of pressure ulcers in community patients (severe pressure ulcer work package) and in the treatment of pressure ulcers (quality of life work package), with service provision identified as a factor that had contributed to severe pressure ulcer development and also impacted on quality of life because of a lack of consideration of patients' needs in the service delivery and organisation of treatment (e.g. unspecified dressing visit times). The severe pressure ulcer findings showed that patients' voices were not sought, or were not heard, when problems arose.

Together, the issues identified from the individual PURPOSE work packages highlight limitations of the standard 'assess, plan, implement and evaluate' model of care. This has led to the development of an active monitoring model of care – Pressure Ulcer Prevention Pathways (PUPPs). PUPPs incorporates risk assessment using the PURPOSE-T (including skin status and pain), the allocation of patients to primary and secondary prevention pathways and active monitoring of individual patients' skin response to preventative interventions. It details required actions and escalation in response to deterioration and pressure ulcer development [see http://medhealth.leeds.ac.uk/accesspurposet (accessed July 2015)].

Wider impacts

In a field characterised by little high-quality research and investment, this programme grant has led to a number of positive impacts that extend beyond the scope of the original award.

Patient and public involvement

The PPI activity and the setting up of PURSUN UK has led to many benefits, as detailed in *Chapter 2*, with examples of innovative engagement. An outcome of the programme grant is the continuation of a sustainable network of service users who are committed to the ongoing development of public and professional awareness of the impact of pressure ulcers and a strong user-driven and supported research agenda.

Isolating the impact of PPI within a research study is notoriously challenging.[303,304] Those challenges are magnified here given the complex nature of a programme grant, in which individual studies feed into and influence each other. The severe pressure ulcer study was the only study in which PPI was formally evaluated. This proved to be very valuable and is something that we would do for the entire programme in future. Despite the challenges we have been able to identify a number of ways in which the involvement of PURSUN UK was helpful (described throughout the monograph and summarised in *Table 91*).

TABLE 91 Benefits of PURSUN UK involvement

Area of impact	Examples
Impact on members of PURSUN UK	• Increased knowledge of research • Increased confidence and self-esteem • Personal satisfaction that improving practice • Better understanding of pressure ulcer prevention and treatment • Building networks • Access to other PPI opportunities • Peer support • Access to training and development opportunities, such as conference attendance
Impact on the project team	• Better understanding of PPI • Better understanding of the impact of treatment, secondary prevention advice and service provision on quality of life and daily living • Better understanding of the long-term impact of severe pressure ulcer development on patients and carers • Partnership working with service users to support public and professional awareness
Management/oversight of the research	• Clearer patient information leaflets (very few changes requested by the ethics committees) • Recruitment of the PPI officer • Development of a PPI strategy for the programme
Conduct of the research	• Development of PURPOSE-T, including the exclusion of albumin and the inclusion of a previous severe pressure ulcer as a direct result of PURSUN UK feedback • Development of the PUQOL-UI instrument • Recruitment of other service users to the PUQOL-UI study • Input into the training of nurses as part of the Risk Assessment Framework through case study development • Data interpretation as part of the severe pressure ulcer work package, feeding into a further implementation project • Data interpretation as part of the pain work package, leading to a further dissemination project
Dissemination/ implementation	• Service user narratives being used as part of dissemination of the pain workstream • Development of video podcasts • Input into the PU-QOL user manual • One member of PURSUN UK has played a pivotal role in the development of a methodology for root cause analyses of severe pressure ulcers
Development of new research	• Development of a HTA programme-funded trial • Themes and ideas generated by PURSUN UK are currently being developed into a new programme of work that will have service user engagement as a theme

We identified these points through the formal severe pressure ulcer PPI evaluation; through ongoing, informal feedback from service users and the project team; by looking at documentation such as e-mails and meeting minutes; and through feedback during the drafting of the monograph.

National Health Service research capacity and capability

The design and delivery of large multicentre projects has extended our original network of NHS research-active centres that have the capacity and research workforce with the clinical knowledge and experience of recruiting the 'hard-to-reach' patient population.

We have had considerable support from a number of NIHR Clinical Local Research Networks and the NIHR Dermatology Specialty Group in terms of set-up and project delivery and this has been maintained with subsequent funding for a NIHR HTA programme-funded trial (PRESSURE 2), with seamless transition of the NIHR infrastructure in key centres.

The programme of studies has facilitated the development of a cohort of tissue viability nurse specialists as new principal investigators as well as partnership with dermatologists who have supported the programme as principal investigators. In addition, the clinical research nurse roles established during the 5-year period have resulted in a number of benefits for the NHS, including the retention of senior clinical nurses, development opportunities for clinical research nurses through local and national dissemination activities and the development of clinical expertise leading to promotion.

The programme grant has also supported the development of three of the programme grant co-applicants (E McGinnis, N Stubbs and L Wilson), who have made a significant contribution to the design and delivery of our nationally and internationally relevant programme of work whilst maintaining substantive NHS nurse specialist/consultant posts. Again, the programme funding supporting their involvement created development opportunities through local part-time secondment opportunities into nurse specialist roles and has enabled the development of capacity, clinical expertise and a team approach to tissue viability service delivery.

Academic research capacity and capability

The programme grant award has led to the development of a cohesive clinical academic research group in Leeds with an ongoing portfolio of research and grant development.

The programme grant award has made a contribution to the successful promotion of four of the co-applicants to professor (J Nixon, EA Nelson, C Dealey and M Briggs), including two promotional chairs and an Honorary Professorship at the Russell Group Universities. This is a major achievement from a professional nursing perspective, which as a profession has low numbers of professorial appointments and very few promotional chairs.

The PURPOSE programme has also supported the development of the programme manager, four research fellows, through their registration as part-time PhD students [C Rutherford (née Gorecki), S Coleman, L Pinkney and C Szoski-Murray], and a trial co-ordinator, who commenced medical school and graduated as a medical doctor (R Stevenson). To date, we have had two successful PhD completions (Rutherford and Coleman).

International collaborations

We have established strong international collaborations through systematic reviews and consensus methods and established the foundation for future collaborative programmes of translational research at the basic science and implementation stages of the translational pathways.

Emerging National Institute for Health Research portfolio

The infrastructure and tools developed during the PURPOSE programme are underpinning an ongoing portfolio of NIHR-funded research. In 2012 the team were successful in a trial grant application to the NIHR HTA programme (PRESSURE 2), securing the clinical academic partnerships and NHS infrastructure for a further 4-year period. The PRESSURE 2 trial is utilising the PURPOSE-T as a method of recording the pressure ulcer risk factor Minimum Data Set and the PU-QOL and PUQOL-UI as secondary outcome measures. Substudies will assess the predictive validity of the PURPOSE-T and the responsiveness of the PU-QOL instrument.

Dissemination and knowledge transfer

We developed a dissemination and knowledge transfer plan for the PURPOSE programme including electronic communications, investigator meetings, publications (see *Acknowledgements*, *Publications*), local, national and international conference presentations (see *Acknowledgements*, *List of presentations and posters*), web-based resources and curriculum development.

Dissemination activity is ongoing. For example, in relation to web-based resources we are currently developing freely available dissemination materials including podcasts, slide packs, case studies and resources for root cause analysis training and posters for use at local events for general dissemination, training and education by NHS providers. In addition, we have set up web access for the three tools that we have developed during this programme of research: the PURPOSE-T, PU-QOL and PUQOL-UI. Web-based access includes copyright agreements and permissions for the use of data for ongoing validation research and guidelines for international translation and validation.

Recommendations

Implications for patient and public involvement in research

1. Patient and public involvement requires explicit commitment to involving service users and their perspectives throughout every aspect of the research process.
2. Presenting research data in live and interactive formats can make the interpretation process more engaging and accessible to service users and support meaningful dialogue between service users and professionals.

Implications for clinical practice development

1. Front-line health-care professionals should respond to patient symptoms including pain (soreness and discomfort), alterations to intact skin and category 1 pressure ulcers and instigate/escalate care provision.
2. Patients with pressure ulcers should have pressure ulcer pain assessment, including type of pain, to inform treatment.
3. In circumstances in which clinicians do not have the skills necessary to address needs, patients should be referred to appropriate colleagues.
4. Some clinicians blamed patients for the development of severe pressure ulcers. In circumstances in which provision of effective pressure ulcer prevention interventions is impacted by a patient's mental capacity or physical disability, advice (consultation) should be sought from colleagues with appropriate multidisciplinary specialist expertise and a problem-solving approach adopted.
5. The development of an electronic version of the PURPOSE-T in health-care settings would facilitate large-scale multivariable modelling and refinement of the PURPOSE-T.
6. Implementation of key research findings may be facilitated through the use of the PUPPS active monitoring model of care, which incorporates risk assessment using the PURPOSE-T (including skin

status and pain), allocation of patients to primary and secondary prevention pathways and active monitoring of individual patients' skin response with required actions and escalation in response to deterioration and pressure ulcer development [see http://medhealth.leeds.ac.uk/accesspurposet (accessed July 2015)].

Implications for quality, safety and health service management

1. To maximise learning, root cause analysis could be extended in two ways:

    i. interview patients and carers to capture their accounts of events
    ii. increase awareness of the possibility that staff are working in contexts in which risky practices are tolerated and be able to assess whether or not this is the case.

2. It is important to co-ordinate services effectively so that pressure ulcer risks are communicated to everyone involved (patients, carers, all members of the multidisciplinary team).
3. Service reconfiguration/ward reorganisation planning needs to ensure continuity of clinical leadership and oversight/delivery of clinical care to high-risk patients.
4. Development of a standardised case ascertainment method in the community setting is required.

Implications for future research

Pain

1. Replication of the pain cohort study is required.
2. The impact of including pain as an indicator for the escalation of preventative interventions requires investigation.

Severe pressure ulcers

1. The severe pressure ulcer study is the first of its kind and findings should be confirmed by further empirical research.
2. There may be merit in studying 'best practice' settings to better understand how patients' and organisational risks are identified and effectively acted on.

Risk assessment

1. Development of objective measurement methods for mechanical boundary conditions, individual susceptibility and tissue tolerance and early indicators of damage.
2. Further evaluation of the PURPOSE-T is required including sensitivity and specificity in different patient populations; impact on decision-making/processes of care; and effectiveness in reducing pressure ulcer incidence in practice.
3. The pressure ulcer risk factor Minimum Data Set should be incorporated into future research.
4. Development of appraisal methods for risk factor research.
5. Development of a lay person version of the PURPOSE-T that can be used by patients and carers to facilitate self-assessment.
6. The impact of including skin status as an indicator for the escalation of preventative interventions requires investigation.

Pressure ulcer quality of life

1. The PU-QOL instrument requires further evaluation through an assessment of responsiveness.
2. The PU-QOL can be used as an outcome measure in future pressure ulcer research (e.g. clinical trials and observational studies) on the proviso that studies have built in a parallel psychometric analysis to indicate the performance (psychometric evaluation) of the scales in future samples.
3. The PU-QOL instrument requires translation and validation for international utilisation.

Pressure ulcer cost–utility analysis

1. The PUQOL-UI can be used in pressure ulcer prevention and treatment trials to enable cost–utility analyses.
2. Further research is required to determine the responsiveness of the PUQOL-UI.
3. Further research is required to establish the benefits of the PUQOL-UI (and other CSUMs) over generic utility measures; this must take into consideration the impact that CSUMs may have on decision-making and efforts to achieve allocative efficiency.
4. Further research is required to determine the extent to which patients completing HRQoL measures consider (and are able to consider) 'disease-attributable' impact only.

Acknowledgements

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Pressure Ulcer Research Service User Network UK

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Chapter 4

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Chapter 5

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Chapter 7

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- University Hospitals Birmingham NHS Foundation Trust: Prof Carol Dealey (PI), Lynne Ellocks (CRN) and Jeannette Marshall (CRN).
- Bradford Teaching Hospitals NHS Foundation Trust: Kathryn Vowden (PI) and Janet McGowan (CRN).
- Burton Hospitals NHS Foundation Trust: Linda Rafter (PI).

- Calderdale and Huddersfield NHS Foundation Trust: Helen Fearnley (PI) and Catherine Smith (CRN).
- County Durham Primary Care Trust and Darlington Primary Care Trust: Richard Buckland (PI).
- Harrogate and District NHS Foundation Trust: Dr Alison Layton (PI) and Margaret Broome (CRN).
- James Paget University Hospitals NHS Foundation Trust: Ingrid Salvery (PI) and Tina Dyble (CRN).
- NHS Kirklees: Tracy Conroy (PI), Alison Murphy (TVNS), Geraldine Thompson (TVNS) and Jackie Ward (CRN).
- NHS Leeds: Nikki Stubbs (PI), Lindsey Worstenholme (CRN), Karen Lamb (CRN), Rachael Lee (CRN) and Julie Thackrey (CRN).
- Leeds Teaching Hospitals NHS Trust: Sally Blundell (CRN), Jimmy Choo (CRN), Andrea Dyer (TVNS), Elizabeth McGinnis (PI) and Kira Meethan (CRN).
- University Hospitals of Leicester NHS Trust: Aiden Dunphy (CRN), Emma Alderman (CRN), Sandra Kazembe (CRN), Bianca Ngwenya (CRN) and Karen Wheafer (PI).
- NHS Leicester County and Rutland Community Health Services: Lynne Spencer (PI).
- Marie Curie Hospice: Jean Gordon (PI).
- Mid Yorkshire Hospitals NHS Trust: Beverly Hemingway (CRN) and Caron Storey (CRN).
- Norfolk and Norwich University Hospital: Helen May (PI) and Susanne McDonald (CRN).
- Northern Devon Healthcare NHS Trust: Melanie Hucker (PI), Geraldine Belcher (CRN), Jane Hunt (CRN) and Amanda Skinner (CRN).
- Northern Lincolnshire and Goole Hospitals NHS Foundation Trust: Helen Blagg (PI).
- North Tees and Hartlepool Hospitals NHS Foundation Trust: Christine Russel (PI).
- Northumbria Healthcare NHS Foundation Trust: Val Henderson (PI), Louise Jones (CRN) and Sean Phillips (CRN).
- North Yorkshire and York NHS Trust: Joyce Simms (PI).
- Scarborough and North East Yorkshire Healthcare NHS Trust: Samantha Haigh (PI).
- Southern Health NHS Foundation Trust: Chantelle Mitchell (CRN).
- South Tyneside NHS Foundation Trust: Jeannette Milne (PI).
- Sussex Community NHS Trust: Claire Cox (PI), Kate Porter (CRN) and Nina Walters (CRN).
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Contributions of authors

Professor Jane Nixon (Professor of Tissue Viability and Clinical Trials Research) was the programme chief investigator and lead for the pain studies. She led the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation and interpretation of data for the pain, severe pressure ulcer, risk assessment, PU-QOL and PUQOL-UI studies; and was involved in drafting *Chapters 1*, *3* and *8* and revising *Chapters 2* and *4–7* critically for intellectual content. She also gave approval to the final version of the monograph and was the guarantor for *Chapters 2*, *3*, *5* and *6*.

Professor E Andrea Nelson (Professor of Wound Healing) was a programme co-applicant. She was involved in the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation and interpretation of data for the pain, severe pressure ulcer, risk assessment and PU-QOL studies; and was involved in revising *Chapters 1–8* critically for intellectual content. She also gave approval to the final version of the monograph.

Dr Claudia Rutherford (née Gorecki) (Research Fellow, Psychometrics) was a programme co-applicant. She was involved in the conception of and was the study lead for the PU-QOL studies including the design, protocol development, co-ordination of all approvals and acquisition of data, data analysis, data interpretation and drafting of *Chapter 6*; contributed to the design, protocol development, data acquisition and drafting of the risk factor systematic review (part of *Chapter 5*); and contributed to protocol development and interpretation of data for the PUQOL-UI study and revision of *Chapter 7* critically for intellectual content. She was also involved in the co-ordination of the monograph and gave approval to the final version.

Dr Susanne Coleman (Programme Manager) was the study lead for the risk assessment studies including design, protocol development, co-ordination of approvals, acquisition of data and data analysis and interpretation and drafting of *Chapter 5*; contributed to the design, protocol development, protocol implementation and interpretation of data for the pain, severe pressure ulcer and PU-QOL studies; and contributed to the revision of *Chapters 3*, *4* and *6* critically for intellectual content. She also gave approval to the final version of the monograph.

Ms Delia Muir (Patient and Public Involvement Officer) was the PPI lead for all projects, set up and co-ordinated the Pressure Ulcer Service User Network UK (PURSUN UK), integrated service user involvement and drafted *Chapter 2* and the PPI activity for all work packages (see *Chapters 1*, *3–8*). She also gave approval to the final version of the monograph.

Professor Justin Keen (Professor of Health Politics) was a programme co-applicant. He was involved in the conception of and was the study lead for the severe pressure ulcer studies including design, protocol development, data analysis and data interpretation and drafting of *Chapter 4*. In addition, he contributed to the design, protocol development, protocol implementation and interpretation of data for the risk assessment study and the revision of *Chapter 5* critically for intellectual content. He was the guarantor for *Chapter 4* and gave approval to the final version of the monograph.

Professor Christopher McCabe (Professor of Health Economics) was a programme co-applicant. He was involved in the conception of and was the study lead for the PUQOL-UI studies including design, protocol development, protocol implementation, data analysis and data interpretation and the revision of *Chapter 7* critically for intellectual content. He was the guarantor for *Chapter 7* and gave approval to the final version of the monograph.

Professor Carol Dealey (Honorary Professor of Tissue Viability and Senior Nurse Researcher) was a programme co-applicant. She was involved in the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation, local co-ordination of approvals and data acquisition for University Hospitals Birmingham NHS Foundation Trust for all work packages; was involved in the interpretation of data for *Chapters 3–6*; and was involved in revising *Chapters 1–8* critically for intellectual content. She also gave approval to the final version of the monograph.

Professor Michelle Briggs (Professor of Nursing) was a programme co-applicant. She was involved in the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation and interpretation of data for the pain study; contributed to drafting and revising of *Chapter 3* critically for intellectual content; and contributed to the design, protocol development, protocol implementation, data analysis (systematic reviews) and interpretation of data for the PU-QOL study and the revision of *Chapter 6* critically for intellectual content. She also gave approval to the final version of the monograph.

Ms Sarah Brown (Principal Medical Statistician) was involved in the design and supervision of the statistical analysis and interpretation of data for the pain cohort study and the Pressure Ulcer Risk Assessment Framework field test and contributed to drafting and revising *Chapters 3* and *5* critically for intellectual content. She also gave approval to the final version of the monograph.

Mrs Michelle Collinson (Senior Medical Statistician) was involved in the design, statistical design and protocol development for all of the pain studies and the statistical analysis and interpretation of data for the two pain prevalence studies and contributed to drafting and revising *Chapter 3* critically for intellectual content.

Professor Claire T Hulme (Professor of Health Economics) was involved in the design, protocol development, co-ordination of approvals, data acquisition, data analysis and data interpretation for the PUQOL-UI study and contributed to drafting and revising *Chapter 7* critically for intellectual content. She also gave approval to the final version of the monograph.

Mr David M Meads (Lecturer in Health Economics) was involved in the design, protocol development, co-ordination of approvals, data acquisition, data analysis and data interpretation for the PUQOL-UI study and contributed to drafting and revising *Chapter 7* critically for intellectual content. He also gave approval to the final version of the monograph.

Dr Elizabeth McGinnis (Tissue Viability Nurse Consultant) was a programme co-applicant. She was involved in the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation and local co-ordination of approvals and data acquisition for Leeds Teaching Hospitals NHS Trust for all work packages; was involved in the interpretation of data for and contributed to the drafting of *Chapters 2–7* critically for intellectual content. She also gave approval to the final version of the monograph.

Dr Malcolm Patterson (Senior Research Fellow) was involved in the design, data analysis and data interpretation from an organisational psychology perspective for the severe pressure ulcer study and contributed to drafting and revising *Chapter 4* critically for intellectual content. He also gave approval to the final version of the monograph.

Ms Carolyn Czoski-Murray (Research Fellow, Health Economics) was involved in the design, protocol development, co-ordination of approvals, data acquisition, data analysis and data interpretation for the PUQOL-UI study and contributed to drafting and revising *Chapter 7* critically for intellectual content. She also gave approval to the final version of the monograph.

Ms Lisa Pinkney (Research Officer) was involved in the design, protocol development, co-ordination of approvals, data acquisition and all field work, data analysis and data interpretation for the severe pressure ulcer study and contributed to drafting and revising *Chapter 4* critically for intellectual content. She also gave approval to the final version of the monograph.

Ms Isabelle L Smith (Medical Statistician) was involved in the statistical design and analysis and interpretation of data for the pain cohort study and the Pressure Ulcer Risk Assessment Framework field test and contributed to drafting and revising of *Chapters 3* and *5* critically for intellectual content. She also gave approval of the final version to the monograph.

Dr Rebecca Stevenson (Trial Co-ordinator and Medical Student) was involved in protocol development, co-ordination of approvals, case report forms and database design, co-ordination of data acquisition and interpretation of analysis for the pain study, was the lead for the community prevalence substudy analysis and contributed to drafting and revising *Chapter 3* critically for intellectual content. She also gave approval to the final version of the monograph.

Mrs Nikki Stubbs (Tissue Viability Nurse Specialist) was a programme co-applicant. She was involved in the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation, local co-ordination of approvals and data acquisition for Leeds Community Healthcare NHS Trust for all work packages; and was involved in the interpretation of data for and the revision of *Chapters 2–7* critically for intellectual content. She also gave approval to the final version of the monograph.

Mrs Lyn Wilson (Programme Manager and Tissue Viability Nurse Specialist) contributed to the design, protocol development, protocol implementation and central co-ordination of approvals and centre set-up for all studies; was involved in the local co-ordination of approvals and data acquisition for Mid Yorkshire Hospitals NHS Trust; and was involved in the interpretation of data for and the revision of *Chapters 2–7* critically for intellectual content. She also gave approval of the final version to the monograph.

Professor Julia M Brown (Professor of Clinical Trials Research) was a programme co-applicant. She was involved in the conception of the PURPOSE programme; contributed to the design, protocol development, protocol implementation and interpretation of data for the pain, risk assessment and PU-QOL studies; and contributed to the revision of *Chapters 3*, *5* and *6* critically for intellectual content. She also gave approval to the final version of the monograph.

Publications

Chapter 2

Muir D. Patient and public involvement in pressure ulcer research. *J Tissue Viability* 2011;**20**:132–3.

Muir D. The Pressure Ulcer Research Service User Network UK (PURSUN UK). *Eur Wounds Manag Assoc J* 2011;**11**:26.

Coleman S, Muir D, Rawson B and Rawson Y. Patient involvement in risk tool development. *Nursing Times* 2015;**111**:17–19.

Chapter 3

Briggs M, Collinson M, Wilson L, Rivers C, McGinnis E, Dealey C, *et al.* The prevalence of pain at pressure areas and pressure ulcers in hospitalised patients. *BMC Nurs* 2013;**12**:19.

Stevenson R, Collinson M, Henderson V, Wilson L, Dealey C, McGinnis E, *et al.* The prevalence of pressure ulcers in community settings: an observational study. *Int J Nurs Stud* 2013;**50**:1550–7.

McGinnis E, Briggs M, Collinson M, Wilson L, Dealey C, Brown J, *et al.* Pressure ulcer related pain in community populations: a prevalence survey. *BMC Nurs* 2014;**13:**16.

Chapter 4

Keen J. Normal accidents: learning how to learn about safety. In Exworthy M, Powell M, Peckham S, Hann A, editors. *Shaping Health Policy: Case Study Methods and Analysis*. Bristol: Policy Press; 2011. pp. 107–18.

Pinkney L, Nixon J, Wilson L, McGinnis E, Stubbs N, Dealey C, *et al.* Why do patients develop severe pressure ulcers? A retrospective case study. *BMJ Open* 2014;**4**:e004303.

Chapter 5

Coleman S, Gorecki C, Nelson EA, Closs J, Defloor T, Halfens R, *et al.* Patient risk factors for pressure ulcer development: a systematic review. *Int J Nurs* 2013;**50**:974–1003.

Coleman S, Nixon J, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* A new pressure ulcer conceptual framework. *J Adv Nurs* 2014;**70**:2222–34.

Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.

Chapter 6

Gorecki CA, Brown JM, Briggs M, Nixon J. The evaluation of 5 search strategies in retrieving qualitative patient-reported electronic data of the impact of pressure ulcers on quality of life. *J Adv Nurs* 2010;**66**:645–52.

Gorecki CA, Lamping DL, Brown JM, Madill A, Firth J, Nixon J. Development of a conceptual framework of health-related quality of life in pressure ulcers: a patient focused approach. *Int J Nurs Stud* 2010;**47**:1525–34.

Gorecki C, Closs J, Nixon J, Briggs M. Patient-reported pressure ulcer pain: a mixed methods systematic review. *J Pain Symptom Manage* 2011;**42**:443–59.

Gorecki C, Lamping D, Nixon J, Brown J, Cano S. Applying mixed methods to pre-test the Pressure Ulcer Quality of Life (PU-QOL) instrument. *Qual Life Res J* 2012;**21**:441–51.

Gorecki C, Nixon J, Madill A, Firth J, Brown J. What influences the impact of pressure ulcers on health-related quality of life? A qualitative patient-focused exploration of contributory factors. *J Tissue Viability* 2012;**21**:3–12.

Gorecki C, Brown J, Cano S, Lamping D, Briggs M, Coleman S, *et al.* Development and validation of a new patient-reported outcome measure for patients with pressure ulcers: the PU-QOL instrument. *Health Qual Life Outcomes* 2013;**11**:95.

Gorecki C, Nixon J, Lamping D, Alvari Y, Brown J. Patient-reported outcome measures for chronic wounds with particular reference to pressure ulcer research: a systematic review. *Int J Nurs Stud* 2014;**51**:157–65.

Rutherford C, Nixon J, Brown JM, Lamping DL, Cano SJ. Using mixed methods to select optimal mode of administration for a patient-reported outcome instrument for people with pressure ulcers. *BMC Med Res Methodol* 2014;**14**:22.

Overall programme

Nixon J, Wilson LM, Coleman S, Gorecki C, Muir D, Pinkney L, *et al.* Pressure ulcer programme of research – PURPOSE. *Eur Wounds Manag Assoc J* 2012;**12**:21–4.

Research nurses

Choo J, Blundell S, McGinnis E. Ethical issues and challenges in pressure ulcer research – the research nurses' perspective. *J Tissue Viability* 2012;**21**:105–8.

Hemingway B, Storey C. The experience of two registered nurses adapting to the role of a clinical research nurse. *Nurs Stand* 2013;**27**:62–8.

Theses

Gorecki CA. *The Development and Validation of a Patient-Reported Outcome Measure of Health-Related Quality of Life for Patients with Pressure Ulcers: PUQOL Project*. PhD thesis. Leeds: University of Leeds; 2011.

Coleman SB. *The Development of a Pressure Ulcer Risk Assessment Framework and Minimum Data Set*. PhD thesis. Leeds: University of Leeds; 2014.

Fell JS. A Secondary Analysis of Pain Presentation and Analgesic Use in the PURPOSE Pressure Ulcer Cohort Study. MSc thesis. Leeds: University of Leeds; 2014.

List of presentations and posters

Chapter 2

Muir D, Nixon J. A different type of expertise; patient and public involvement in pressure ulcer research. 14th Annual EPUAP Conference, Oporto, Portugal, September 2011 (oral presentation).

Muir D, McGoverin A, Rawson B. The Pressure Ulcer Research Service User Network. PURPOSE Principal Investigators Training Day, Leeds, UK, December 2011 (oral presentation).

Muir D, Bennett C. Pressure ulcer patient stories. Tissue Viability Society Conference, Kettering, UK, April 2012 (oral presentation, invited speaker).

Muir D, Bell P, Bennett C, Pickersgill A, Rawson Y, Rawson B, *et al.* Patient and public involvement in pressure ulcer research: lessons learnt and next steps. Tissue Viability Society Conference, Kettering, UK, April 2012 (oral presentation).

Muir D, Pinkney L, McGoverin A, Parker S. Performing an enquiry: an innovative model for involving people in the interpretation of research data. INVOLVE Conference, Nottingham, UK, November 2012 (workshop).

Muir D. Bringing research to life: involving service users in the severe pressure ulcer project. Tissue Viability Society Conference, Kettering, UK, April 2013 (poster presentation).

Muir D. Bringing research to life: involving service users in the severe pressure ulcer project. Involving People Annual Meeting, Cardiff, UK, March 2013 (poster presentation).

Muir D, Rawson B, Rawson Y. Living with a pressure ulcer – a patient and carer perspective. Stop the Pressure Student Conference, Lincoln, UK, October 2013 (oral presentation, invited speaker).

Chapter 3

Nixon J, Wilson L, on behalf of the PURPOSE Project Team. Pressure ulcer pain suffering: issues raised in a multi-centre prevalence. 13th EPUAP Open Meeting, Birmingham, UK, September 2010 (oral presentation, invited speaker).

Nixon J, on behalf of the PURPOSE Project Team. Understanding prevalence of localized pressure ulcer related pain. Tissue Viability Society Conference, Kettering, UK, April 2011 (oral presentation, invited speaker).

Nixon J, on behalf of the PURPOSE Pain Team. Pressure ulcer pain prevalence in community populations: prevalence survey. 14th Annual EPUAP Conference, Oporto, Portugal, September 2011 (oral presentation).

Briggs M, on behalf of the PURPOSE Project Team. The prevalence of pain and pressure ulcers in hospitalized patients; results of a national survey. British Pain Society Annual Scientific Meeting, Liverpool, UK, April 2012 (poster; awarded best poster prize).

Stevenson R, Collinson M, Henderson V, Cozens J, Nixon J. Pressure ulcers in the community: a multicentre prevalence study. 15th Annual EPUAP Conference, Cardiff, UK, September 2012 (oral presentation; winner of the student oral competition).

Nixon J, on behalf of the PURPOSE Pain Team. The prevalence of pressure area and pressure ulcer pain in hospitalised patients. 13th NPUAP Biennial Conference, Houston, TX, USA, February 2013 (poster presentation).

McGinnis E, Nixon J, Briggs M, Collinson M, Wilson L, Rivers C, *et al.* Prevalence of pressure ulcer pain in community patients. 13th NPUAP Biennial Conference, Houston, TX, USA, February 2013 (poster presentation).

Nixon J. Is pain a predictor of category 2 pressure ulcers? Results of the PURPOSE Pain Cohort Study. Tissue Viability Society Conference, Kettering, UK, April 2013 (oral presentation, invited speaker).

Nixon J, Smith I, Brown S, Nelson EA, McGinnis E, Stubbs N, *et al.*, on behalf of the PURPOSE Pain Cohort Group. Is pain a predictor of category 2 pressure ulcers? Results of the PURPOSE Pain Cohort Study. 16th Annual EPUAP Conference, Vienna, Austria, September 2013 (oral presentation).

Muir D, Briggs M, McGinnis E and Nixon N. Pain and pressure ulcer development: the service user perspective. TVS Conference, York, 2014 (oral presentation).

Nixon J, Smith I. Is pain a predictor of Category 2 pressure ulcers? Analysis of skin site level data from the PURPOSE Pain Cohort Study, TVS Annual Conference, York, April 2014 (oral presentation).

Smith I, Brown S, McGinnis E, Stubbs N, Nixon J on behalf of the PURPOSE Pain Cohort Group. Is pain a predictor of Category 2 pressure ulcers? Analysis of skin site level data from the PURPOSE Pain Cohort Study, 17th EPUAP Meeting, Stockholm, August 2014 (oral presentation).

Smith I, Brown S, McGinnis E, Stubbs N, Nixon J on behalf of the PURPOSE Pain Cohort Group. What is the extent of pain suffering, and is pain predictive of pressure ulcer development? 25th Conference of the European Wound Management Association, London, May 2015 (oral presentation, invited speaker).

Chapter 4

Pinkney L, Keen J, Nixon J. Why do patients develop severe pressure ulcers? Leeds Institute of Health Sciences Research Postgraduate Symposium, Leeds, UK, June 2010 (oral presentation).

Pinkney L, Keen J, Nixon J. Why do patients develop severe pressure ulcers? BMJ International Forum on Quality and Safety in Healthcare, Amsterdam, Netherlands, April 2011 (poster presentation).

Pinkney L, on behalf of the Severe Pressure Ulcer Project Team. Do organizations cause pressure ulcers? An exploratory review. 14th Annual EPUAP Conference, Oporto, Portugal, September 2011 (oral presentation).

Keen J, on behalf of the Severe Pressure Ulcer Project Team. Severe pressure ulcers: how organisational contexts influence their development. Tissue Viability Society Conference, Kettering, UK, April 2013 (oral presentation).

Dealey C, Keen K, Nixon J, on behalf of the Severe Pressure Ulcer Project Team. Why do patients develop severe pressure ulcers? 16th Annual EPUAP Conference, Vienna, Austria, September 2013 (oral presentation).

Keen J. Why do patients develop severe pressure ulcers? EWMA, London, May 2015 (oral presentation).

Chapter 5

Coleman S, Nixon J, Gorecki C, Nelson EA, on behalf of the PURE Collaborative Group. A systematic review of pressure ulcer risk factors. 14th Annual EPUAP Conference, Oporto, Portugal, September 2011 (oral presentation).

Coleman S, Wilson L, on behalf of the PURAF Project Team. Pressure ulcer risk assessment. Building Blocks of Wound Care Conference North East Tissue Viability Nurses Regional Group, Leeds, UK, September 2011 (oral presentation, invited speaker).

Coleman S. The development of pressure ulcer minimum data set (PU-MDS) using consensus methods. Postgraduate Research Conference, Leeds, UK, December 2012 (oral presentation)

Colman S, on behalf of the PURAF Project Team. Systematic review of pressure ulcer risk factors. 13th NPUAP Biennial Conference, Houston, TX, USA, February 2013 (poster presentation).

Coleman S. From systematic review to clinical practice – risk factor domains to be considered in pressure ulcer risk assessment. Tissue Viability Society Conference, Kettering, UK, April 2013 (oral presentation, invited speaker).

Coleman S, Nixon J, Nelson EA, Farrin A, on behalf of the PURAF Study Group. From systematic review to clinical practice: using consensus methods to develop a Pressure Ulcer Risk Assessment Framework (PURAF). 16th Annual EPUAP Conference, Vienna, Austria, September 2013 (oral presentation).

Coleman S, Nixon J, Nelson EA, Farrin A, on behalf of the PURAF Study Group. The design and pre-testing of a Pressure Ulcer Risk Assessment Framework (PURAF). 16th Annual EPUAP Conference, Vienna, Austria, September 2013 (oral presentation).

Coleman S, Stubbs N, McGinnis E and Nixon J on behalf of the PUPPs and PURPOSE T Implementation Team. Pressure Ulcer Prevention Pathways (PUPPs) and Pressure Ulcer Risk Primary Or Secondary Evaluation Tool (PURPOSE T). TVS, York, April 2014 (workshop).

Coleman S and Nixon J. Translational gap: measuring risk factors in clinical practice, 2nd EPUAP Focus Meeting on Skin Health and Microclimate. Southampton, April 2014, (oral presentation, invited speaker).

Nixon J and Coleman S. Pressure ulcer recognition and prevention: the value of risk assessment. Stop the pressure student conference, Leeds, June 2014 (oral presentation, invited speaker).

Coleman S and Nixon J on behalf of the PUPPs and PURPOSE T Implementation Team. Active monitoring model of care incorporating PURPOSE T Workshop, 17th EPUAP Meeting, Stockholm, Aug 2014 (oral presentation, invited speaker).

Coleman S on behalf of the PURPOSE RAF Project Team. Risk factors in context: from conceptual framework to risk assessment in practice, 17th EPUAP Meeting, Stockholm, August 2014 (oral presentation, invited speaker).

Coleman S. The development of PURPOSE T. Pressure ulcer research: dissemination and implementation conference, Leeds, February 2015 (oral presentation, invited speaker).

Coleman S behalf of the PUPPs and PURPOSE T Implementation Team. PURPOSE T Master Class. Academic Health Science Network, Patient Safety Collaborative: Pressure Damage learning collaborative, Sussex, May 2015 (workshop, invited speaker).

Coleman S and McGinnis E on behalf of the PUPPs and PURPOSE T Implementation Team. Evidenced-based pressure ulcer risk assessment and implementation in clinical practice. EWMA 2015, London, May 2015 (workshop).

Coleman S, Muir D, Rawson B and Rawson Y. Involving patients in pressure ulcer prevention. Patient Safety Congress, Birmingham, July 2015 (oral presentation).

Nixon J and Coleman S, Translation of pressure ulcer risk factor research into practice. Posture and Mobility Group Conference, Leeds, July 2015 (oral presentation, invited speaker).

Chapter 6

Gorecki C, Brown J, Nelson EA, Briggs M, Dealey C, Schoonhoven L, *et al.* A systematic review of pressure ulcers and quality of life. EPUAP Open Meeting, Oxford, UK, August 2007 (oral presentation).

Gorecki C, Brown J, Nelson EA, Briggs M, Dealey C, Schoonhoven L, *et al.* A systematic review of pressure ulcers and quality of life. 14th Annual Conference of the International Society of Quality of Life, Toronto, Canada, October 2007 (poster presentation).

Gorecki C, Brown J, Briggs M, Nixon J. Evaluation of 5 search strategies to locate subjective patient-reported HRQoL data. 14th Annual Conference of the International Society of Quality of Life, Toronto, Canada, October 2007 (poster presentation).

Gorecki C, Brown J, Lamping D, Nelson EA, Briggs M, Dealey C, *et al.* Pressure ulcers and quality of life: systematic review and preliminary results from a qualitative study. Tissue Viability Society Annual Conference, Peterborough, UK, April 2008 (oral presentation, invited speaker).

Gorecki C, on behalf of the PUQOL Project Team. Existing outcome measures used in pressure ulcers. 12th Annual EPUAP Open Meeting, Amsterdam, the Netherlands, September 2009 (oral presentation).

Gorecki C, Brown J, Lamping D, Madill A, Firth J, Nixon J, on behalf of the PUQOL Project Team. Health-related quality of life in pressure ulceration: development of a conceptual framework. 16th Annual Conference of the International Society for Quality of Life Research, New Orleans, LA, USA, October 2009 (oral presentation).

Gorecki C, Brown J, Lamping D, Nixon J. Using cognitive interviewing to improve a newly developed health-related quality of life patient-reported outcome for people with pressure ulcers. 16th Annual Conference of the International Society for Quality of Life Research, New Orleans, LA, USA, October 2009 (poster presentation).

Gorecki C, Closs J, Nixon J, Briggs M. Patient-reported pressure ulcer-associated pain: a mixed-methods systematic review. British Pain Society Annual Scientific Meeting, Manchester, UK, April 2010 (poster presentation).

Briggs M, Gorecki C, Nixon J, Closs SJ. Words used to describe pressure ulcer pain: the results of a systematic review and qualitative synthesis. 13th EPUAP Open Meeting, Birmingham, UK, September 2010 (oral presentation).

Gorecki C. EPUAP Novice Award Lecture 2010. What constitutes health-related quality of life in pressure ulcers and how do we measure it? 13th EPUAP Open Meeting, Birmingham, UK, September 2010 (oral presentation, invited speaker).

Gorecki C, Lamping DL, Nixon J, Brown J, Cano S. The benefits of mixed methods in scale development I: the added value of Rasch analysis in pre-testing. 17th Annual Conference of the International Society for Quality of Life Research, London, UK, October 2010 (poster presentation).

Gorecki C, Nixon J, Lamping DL, Brown J, Cano S. The benefits of mixed methods in scale development II: selecting optimal mode of administration. 17th Annual Conference of the International Society for Quality of Life Research, London, UK, October 2010 (oral presentation, invited speaker).

Firth J, Briggs M, Nelson EA, Gorecki C. Health-related quality of life in patients with rheumatoid arthritis and foot ulceration: care pathways and experiences of care provision. British Health Professionals in Rheumatology Conference, Brighton, UK, April 2011 (poster presentation).

Gorecki C. Challenges in measuring HRQoL in pressure ulcers: development of a PRO measure. Tissue Viability Society Conference, Kettering, UK, April 2011 (oral presentation).

Claudia Gorecki. Development of a patient-reported outcome measure: impact of pressure ulcers on HRQoL. Royal College of Nursing International Conference, Harrogate, UK, May 2011 (oral presentation).

Briggs M, Firth J, Nelson EA, Gorecki, C. Pain and foot ulceration in rheumatoid arthritis; how do patients describe the experience? British Pain Society Annual Conference, Edinburgh, UK, June 2011 (oral presentation).

Gorecki C. Application of mixed methods in early rating scale development. International Rasch Expert Group Meeting, Dubrovnik, Croatia, June 2011 (oral presentation, invited speaker).

Gorecki C, Nixon J, on behalf of the PUQOL Project Team. PU-QOL: a patient-reported outcome measure of health-related quality of life for patients with pressure ulcers. 14th Annual EPUAP Conference, Oporto, Portugal, September 2011 (oral presentation).

Nelson EA, Nixon J, Coleman S, Gorecki C. Pressure ulcer epidemiology, pain and quality of life. 4th Congress of the World Union of Wound Healing Societies, Yokohama, Japan, September 2012 (oral presentation).

Nixon J, Gorecki C, on behalf of the PUQOL Project Team. Final version of a patient-reported outcome measure of health-related quality of life for patients with pressure ulcers (PUQOL). 13th NPUAP National Biennial Conference, Houston, TX, USA, February 2013 (poster presentation).

Rutherford C on behalf of the PUQOL project team. A patient-reported outcome measure of health-related quality of life for patients with pressure ulcers: the PU-QOL instrument. The 4th Australasian Wound and Tissue Repair Society Conference, Queensland, Australia, May 2014 (oral presentation).

Chapter 7

Czoski-Murray C, Meads D, Edlin R, Hulme C, Gorecki C, Nixon J, *et al.* Constructing a utility algorithm for the Pressure Ulcer Quality of Life – Utility Instrument (PuQol-UI). TVS conference, York, April 2014 (oral presentation).

Overall programme

Nixon J, on behalf of the PURPOSE Collaborative Group. Pressure UlceR Programme Of ReSEarch. Tissue Viability Society Annual Conference, Llandudno, UK, April 2009 (oral presentation).

Nixon J, Keen J, McCabe C, Nelson A, Dealey C, Briggs M, *et al.* PURPOSE – Pressure UlceR Programme Of reSEarch. Nursing and Midwifery Conference, Leeds, UK, May 2009 (poster presentation).

Nixon J, on behalf of the PURPOSE Collaborative Group. Pressure UlceR Programme Of ReSEarch. Yorkshire and the Humber Directors of Nursing Network Meeting, York, UK, June 2009 (oral presentation).

Nixon J, on behalf of the PURPOSE Collaborative Group. Pressure UlceR Programme Of ReSEarch. A Practical Guide to Reducing Healthcare Associated Pressure Ulcers, Manchester, UK, July 2009 (oral presentation, invited speaker).

Wilson L, Coleman S, on behalf of the PURPOSE Collaborative Group. Pressure UlceR Programme Of reSEarch (PURPOSE). Wounds UK 2009 Wound Care Conference, Harrogate, UK, November 2009 (oral presentation).

Nixon J Wilson L, Coleman S Gorecki C Nelson A, on behalf of the PURPOSE team. Pressure UlceR Programme Of reSEarch (PURPOSE). 13th EPUAP Open Meeting, Birmingham, UK, September 2010 (poster presentation).

Muir D, Nixon J, on behalf of the PURPOSE team. A different type of expertise; patient and public involvement in pressure ulcer research. Royal College of Nursing International Nursing Research Conference, Harrogate, UK, May 2011 (Symposium: programmatic research in pressure ulcer prevention; update on progress and how we are addressing challenges).

Nelson EA, Coleman S, Nixon J, on behalf of the PURPOSE team. Challenges in identifying risk factors for pressure ulceration: systematic review of risk factors and problems addressed. Royal College of Nursing International Nursing Research Conference, Harrogate, UK, May 2011 (Symposium: programmatic research in pressure ulcer prevention; update on progress and how we are addressing challenges).

Nixon J, on behalf of the PURPOSE Pain Team. Pressure ulcer pain suffering: issues raised in a multi-centre pain prevalence study. Royal College of Nursing International Nursing Research Conference, Harrogate, UK, May 2011 (Symposium: programmatic research in pressure ulcer prevention; update on progress and how we are addressing challenges)

Nixon J, Wilson L, Coleman S, Gorecki C, Nelson EA, on behalf of the PURPOSE team. Pressure UlceR Programme Of reSEarch – PURPOSE. Royal College of Nursing International Nursing Research Conference, Harrogate, UK, May 2011 (Symposium: programmatic research in pressure ulcer prevention; update on progress and how we are addressing challenges)

Nixon J, Choo J, McGinnis E, Nelson EA, on behalf of the PURPOSE team. Pressure UlceR Programme Of reSEarch (PURPOSE). 2nd International Nursing Research Conference, University of Malaya, Malaysia, February 2012 (poster presentation).

Nelson EA, Nixon J, Coleman S, Gorecki C. Pressure ulcer epidemiology, pain and quality of life. 4th Congress of the World Union of Wound Healing Societies, Yokohama, Japan, September 2012 (oral presentation).

Wilson L. High impact actions – PURPOSE. E4E Conference, Mid Yorkshire Hospitals NHS Trust, UK, September 2012 (oral presentation).

McGinnis E, Stubbs N, Coleman S, Muir D, Ginn C, Hinchcliffe S, Nixon J. Pressure ulcer research: dissemination and implementation conference, LGI, Leeds, 5 February 2015 (oral presentation).

Research nurses

Storey C, Hemingway B. Reflections on the clinical research nurse role. Tissue Viability Society Conference, Kettering, UK, April 2011 (poster presentation; awarded best poster prize).

Choo J, Blundell S, McGinnis E. Ethical issues and challenges in pressure ulcer research – the research nurses' perspective. Tissue Viability Society Conference, Kettering, UK, April 2012 (poster presentation).

Awards

- EPUAP Senior Investigator Award 2012 – Professor Carol Dealey.
- EPUAP Novice Investigator Award 2010 – Dr Claudia Rutherford (née Gorecki).
- Poster prize – Storey C, Hemingway B. Reflections on the clinical research nurse role. Tissue Viability Society Conference, Kettering, April 2011.
- Poster prize – Briggs M, on behalf of the Project Team. The prevalence of pain and pressure ulcers in hospitalized patients; results of a national survey. British Pain Society Annual Scientific Meeting, Liverpool, April 2012.
- Student oral competition – Stevenson R, Collinson M, Henderson V, Cozens J, Nixon J. Pressure ulcers in the community: a multicentre prevalence study. 15th Annual EPUAP Conference, Cardiff, September 2012.
- Poster prize – McGinnis E, Nixon J, Briggs M, Collinson M, Wilson L, Rivers C, *et al.* Prevalence of pressure ulcer pain in community patients. 13th NPUAP National Biennial Conference, Houston, TX, USA, February 2013.

Data sharing statement

Requests for data should be made to the corresponding author.

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Appendix 1 Recruitment by participating centre

Name of trust	Name of centre	Pain prevalence	Pain cohort	Severe project	PURAF field test	PU-QOL qualitative study	PUQ-OL pre-test	PU-QOL field test 1	PU-QOL field test 2	PUQOL-UI method substudy	Trust total
1. Leeds Teaching Hospitals NHS Trust	Leeds General Infirmary	730	57	1	16	8	9	11	9	6	1810
	St James's University Hospital	760	52	1	42			3	10	4	
	Chapel Allerton Hospital	52	9								
	Wharfedale Hospital	25	4					1			
2. Newcastle and North Tyneside PCT		1680	1			2	4	19			1706
3. University Hospitals Birmingham NHS Foundation Trust	Queen Elizabeth Hospital	447	59		22		4	45	25	15	1047
	Selly Oak Hospital	417	12				1				
4. Mid Yorkshire Hospitals NHS Trust	Pinderfields General Hospital	443	86	1	14	6	7	27	18	8	1167
	Pontefract Hospital	225	8				1	3	2		
	Dewsbury and District Hospital	298	7					4	1		
	Rehabilitation Hospital Queen Elizabeth House		8								
5. Northumberland Care Trust (Northumbria Healthcare Trust as of 1 April 2011)		103	41		14			30	30	23	241
6. Leeds Community Healthcare NHS Trust			27	2	54	3		24	15	13	138
7. Sussex Community NHS Trust	Sussex Community NHS Trust				34					12	97
	Brighton General Hospital		51								

Name of trust	Name of centre	Pain prevalence	Pain cohort	Severe project	PURAF field test	PU-QOL qualitative study	PUQ-OL pre-test	PU-QOL field test 1	PU-QOL field test 2	PUQOL-UI method substudy	Trust total
8. Calderdale and Huddersfield NHS Foundation Trust	Calderdale Royal Hospital		16						5		38
	Huddersfield Royal Infirmary		13					1	3		
9. Calderdale and Huddersfield PCT			2					3	3		8
10. Kirklees PCT			43					17	17		77
11. Bradford Teaching Hospitals NHS Foundation Trust	Bradford Royal Infirmary		26	1				30	20		77
12. County Durham and Darlington PCT			28			3	4	18	15		68
13. Harrogate and District NHS Foundation Trust	Harrogate District Hospital		37		14				3	3	57
14. Wakefield District PCT			5		20			13	7		45
15. University Hospitals of Leicester NHS Trust	Leicester Royal Infirmary		16					2	10		28
16. Norfolk and Norwich University Hospitals NHS Foundation Trust	James Paget Hospital								11		26
	Norfolk and Norwich University Hospital							10	5		
17. North Lincolnshire and Goole NHS Foundation Trust	Scunthorpe General Hospital							4			18
	Diana Princess of Wales Hospital							10	4		
18. North Devon District Hospital	North Devon District Hospital		17								17
19. Leicester and Rutland PCT			2					6	3		11
20. South Tyneside NHS Foundation Trust	South Tyneside NHS Foundation Trust									10	10
21. Walsall PCT						5	5				10

Name of trust	Name of centre	Pain prevalence	Pain cohort	Severe project	PURAF field test	PU-QOL qualitative study	PUQ-OL pre-test	PU-QOL field test 1	PU-QOL field test 2	PUQOL-UI method substudy	Trust total
22. Scarborough and North East Yorkshire NHS Trust	Scarbourgh General Hospital			1					7		9
	Bridlington and District Hospital								1		
23. Burton Hospitals NHS Foundation Trust	Queen's Hospital		7								7
24. Southern Health NHS Foundation Trust	Southern Health NHS Foundation Trust									6	6
25. Southport and Ormskirk Hospital NHS Trust	Southport and Formby District General Hospital							2	4		6
26. Belfast Health and Social Care Trust	Musgrave Park Hospital SCI Unit					4					5
	Royal Victoria Hospital, Belfast					1					
27. Ayrshire and Arran Health Board	Crosshouse Hospital								2		2
28. North Tees and Hartlepool Hospitals NHS Foundation Trust	University Hospital of Hartlepool							0	1		2
	University Hospital of North Tees							1	0		
29. North Yorkshire and York PCT				1							1
30. Marie Curie	Marie Curie Hospice Bradford							1			1
Total		5180	634	8	230	32	35	285	231	100	6735

PCT, Primary Care Trust; PURAF, Pressure Ulcer Risk Assessment Framework; SCI, spinal cord injury.

Appendix 2 Pressure Ulcer Research Service User Network UK information leaflet

PURSUN
The Pressure Ulcer Research Service User Network UK

The Pressure Ulcer Research Service User Network UK

PURSUN UK

Information for patients, carers and service users

Get Involved

If you would like to join our network, or just get some more information then contact:

Delia Muir
Patient and Public Involvement Officer

Clinical Trials Research Unit (CTRU)
University of Leeds
Leeds
LS2 9JT

0113 343 8609

d.p.muir@leeds.ac.uk

The Clinical Trials Research Unit (CTRU) is based at the University of Leeds. The unit works on research projects across the NHS. One of our key areas of work is pressure ulcer research.

Preparation, Support and Development

We have a Patient and Public Involvement Officer, who will offer on-going support and mentoring based on your individual needs. We try to make our activities as accessible and engaging as possible and create a supportive environment for our members.

Being a member of the network can also provide access to development opportunities such as workshops, training and conferences.

ctru

UNIVERSITY OF LEEDS

Pressure Ulcers

Pressure ulcers (sometimes called bed sores or pressure sores) are mainly caused by lying / sitting in one position for a long period of time. They are a complication of other serious illnesses, injuries and long term conditions.

Pressure ulcers can cause a great deal of discomfort and distress for patients, as well as those caring for them. We are committed to raising awareness of the problems which pressure ulcers cause and improving care through research. We believe that the unique perspectives of patients, carers and service users are a vital part of this work.

What is PURSUN UK?

We are a network of people with personal experience living with or being at a high risk of pressure ulcers. This can be as a patient, carer or family member. We work in partnership with researchers and clinicians to help plan and carry out research.

We have a minimum of two general meetings a year. Other opportunities are sent out to members as they arise. There are a variety of ways to get involved. Including:

- Developing clear patient materials. This can be done at home by phone, post or email
- Developing new research ideas
- Helping to make sense of research findings from the service user perspective
- Becoming a member of research committees
- Representing the network at meetings and events

No previous experience of research is needed and not all members of the network are expected to be involved in all areas of work. We will work together to find the level of commitment which is right for you.

What's in it for you?

Being part of the network will give you the chance to:

- Help researchers and health professionals better understand the experiences of patients, carers and service users
- Help make sure pressure ulcer research is relevant to the public
- Help make sure pressure ulcer research is carried out in a respectful way
- Meet other people who are in a similar situation to you
- Learn more about research and build your skills

Payment and expenses

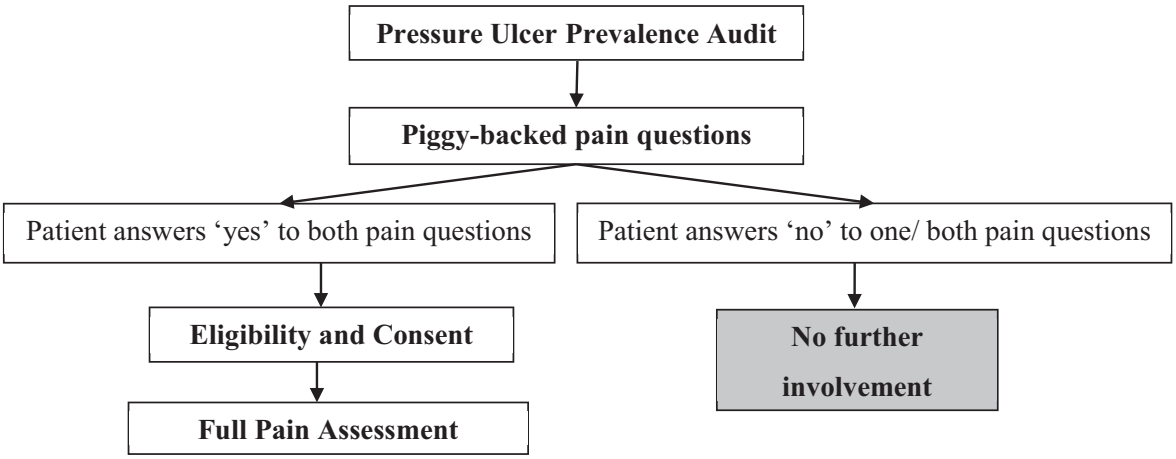
- Travel expenses will be reimbursed
- Any printing or postage costs will be reimbursed when working from home
- many of the research opportunities offered also include a fee for your time
- We are happy to discuss how payment may affect benefits

Appendix 3 Pain prevalence study reduced format protocol

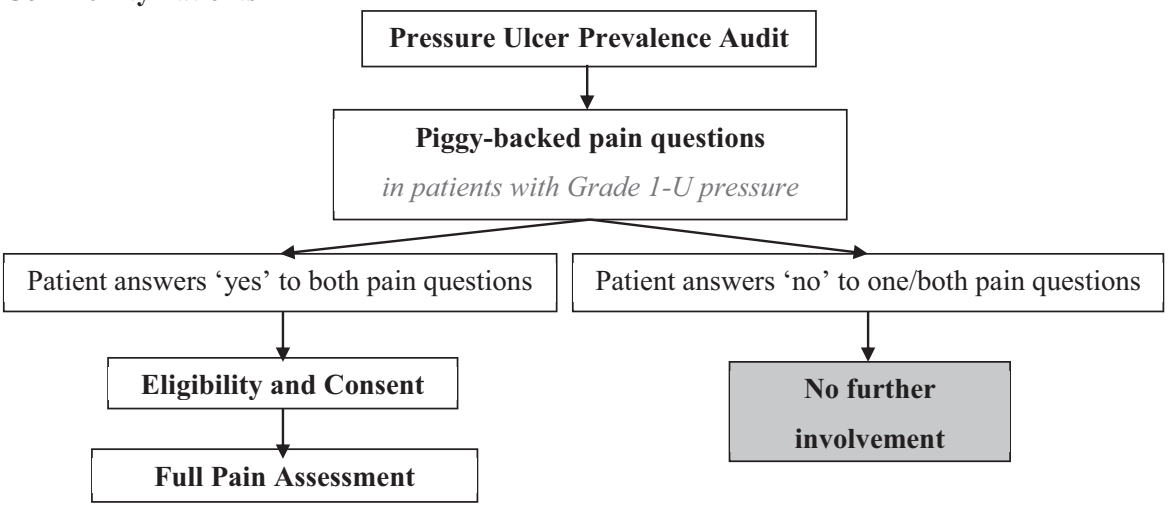
NB: This study protocol (version 3, dated 18 Jan 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to serious adverse events, data monitoring, quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, and publication policy are available upon request

3 Flow diagram

Hospital Patients



Community Patients



5 Objectives

The objectives of this study are to:

1. determine the prevalence of localised PU pain in 'pressure areas'.
2. assess the type and severity of localised PU pain in 'pressure areas' in patients with clinically assessed normal skin and Grade 1-U PUs (see Table 1)
3. explore the association between pain and skin classification.

Table 1. EPUAP Pressure Ulcer Classification System[4]. For the purpose of the research the classification has been adapted to enable grading of normal skin and unstageable pressure ulcers.

Grade	Description
Grade 0	Normal skin
Grade 1	Non-blanchable erythema of intact skin Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade 2	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.
Grade 3	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through underlying fascia.
Grade 4	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.
Grade U	Unstageable. Full thickness skin loss in which *actual* depth of the ulcer is *completely* obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

6 Methods

6.1 Design

We plan to undertake pain prevalence surveys in acute and community NHS Trusts. We will piggy-back questions on pain onto the routine annual PU prevalence audits in NHS Trusts. Anonymised individual patient data is recorded by a ward/community nurse. In addition to the standard PU data, patients will be asked two questions relating to localised skin pain to establish PU pain prevalence. Where pain is indicated, consenting patients will undergo a detailed pain assessment using the adapted Leeds Assessment of Neuropathic Symptoms and

Signs (LANSS) Pain Scale (Appendix 2)[8,9] and a numerical rating scale for pain severity[10,11]. Skin classification will also be verified. This will establish the type and severity of localised PU pain and skin classification.

6.2 Eligibility

6.2.1 Routine PU Prevalence Audit

As per standard PU prevalence audit methodology all inpatients/community nursing case-load patients on the date or period of the participating Trust's PU prevalence audit that are 18 years of age or older are included. Patients in paediatric, obstetric, and psychiatric care settings will be excluded.

6.2.2 PU Pain Prevalence Audit – Hospital

Patients will be eligible for the two pain questions where they are considered well and able to report the presence or absence of localised skin pain, by the clinical team. Patients will be excluded from the two pain questions where it is considered ethically or clinically inappropriate by the clinical team, for example, very sick patients or those where death is imminent.

6.2.3 PU Pain Prevalence Audit – Community

Patients will be eligible for the two pain questions where they have a skin area assessed as a Grade 1-U pressure ulcer and are considered well and able to report the presence or absence of localised skin pain, by the clinical team. Patients will be excluded from the two pain questions where it is considered ethically or clinically inappropriate by the clinical team, for example, very sick patients or those where death is imminent.

6.2.4 Full Pain and Skin Assessment

Patients who reply 'yes' to both pain prevalence questions will be eligible for the full pain and skin assessment. Patients will be excluded where it is considered ethically or clinically inappropriate by the clinical team, for example, very sick patients or those where death is imminent. Patients will also be excluded if they are unable to provide consent.

6.3 Assessments and Data Collection

6.3.1 Routine PU Prevalence Audit

Standard practice for the PU prevalence audit will be used to assess and record data. Anonymised individual patient data will be recorded by a ward/community nurse who is trained in the use of the data collection form and skin assessment as part of the PU prevalence audit preparation and planning. In the hospital setting all patients are assessed on one designated day. In the community setting all patients are assessed over a one-two week period.

Data recorded will include:

- Name of Trust
- Ward Speciality/Community Setting
- Date of birth
- Gender
- Ethnicity
- Height
- Weight
- Mobility
- Risk Assessment Scale (as per local policy)
- Skin classification by skin site
- Hospital or community acquired
- Present on this hospital admission/community referral
- Prevention/treatment interventions

6.3.2 PU Pain Prevalence Audit

In addition, the ward/community nurse will consider whether each patient is well and able to report the presence or absence of localised skin pain. Where patients are assessed as not able to report pain this will be noted. Patients assessed as able will be asked the following two questions:

1. At any time, do you get pain, soreness, or discomfort on a pressure area? (*Prompt*: back, bottoms, hips, elbows, heels, or other as applicable to patient.)?
2. Do you think this is related to either: your pressure sore OR laying in bed for a long time OR sitting for a long time?

6.3.3 Full Pain and Skin Assessment

Patients who reply 'yes' to both of the pain prevalence questions will be flagged to a member of the Trust Tissue Viability Team (TVT; Tissue Viability Nurse

Consultant/Specialist/Research Nurse), and, subject to their consent, will have a full pain assessment and verification of skin assessment.

Patients will be asked about pain for all pressure area sites using a numerical rating scale[8,9] for pain intensity (for most severe pain over the past week).

Up to two skin areas will be assessed using the Leeds Assessment Neuropathic Symptoms and Signs (LANSS) Pain Scale[10,11] (Appendix 2). The LANSS Scale[10] (Appendix 2) consists of a brief clinical assessment and is easy to score in the clinical setting. The questionnaire contains 5 symptom items and 2 clinical sensory testing items associated with neuropathic pain. The LANSS is a clinically validated tool which allows assessment of neuropathic and inflammatory pain, and has been used in a wide variety of clinical settings[11]. The two sites assessed using the LANSS will include the most painful skin site located on the torso (i.e. sacrum, buttocks, ischial tuberosities, hips) and the most painful site located on a limb (i.e. heels, elbows).

In addition patients will be asked if they have been offered any treatment for pain. Skin assessments undertaken by the ward/community nurse for the PU prevalence audit will be verified through nursing records or clinical assessment by the Trust TVT member.

6.4 Consent

6.4.1 Routine PU and PU Pain Prevalence Audit

Anonymised data from all patients will be collected as part of the PU and PU pain prevalence audit, and consent will not be obtained.

6.4.2 Full Pain and Skin Assessment

Patients responding ‘yes’ to the two pain prevalence questions (section 6.3.2) will be provided with verbal and written details about the more detailed pain assessment and will be asked to provide consent for this study. The verbal explanation of the study and Patient Information Sheet and Consent Form will be provided by the attending clinical staff or a member of the Trust TVT for the patient to consider. This will include detailed information about the rationale, design, and personal implications of the study. Following information provision, patients will have as long as they need to consider participation and will be given the opportunity to discuss the study with their family and other healthcare professionals before they are asked whether they would be willing to take part in the study.

Patients will then be invited to provide informed, written consent. A record of the consent process detailing the date of consent will be kept in the patient healthcare records. Assessment of eligibility and informed consent will usually be undertaken by a member of the Trust TVT. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment.

Should the patient be capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member or friend of the patient, or another member of the patient's healthcare team who is not directly involved in the research study.

The original consent form will be retained in the Investigator Site File, a copy of the consent will be given to the patient and a second copy filed in the patient healthcare notes.

6.4.3 Non-participation

An anonymised log of all patients who are considered for full pain assessment but who do not participate will be collected, including reason for non-participation.

7 Statistical Considerations

7.1 Sample size

Our aim in this study is to assess the prevalence of PU pain in hospital and community patient populations. We will piggy-back this work onto routine PU prevalence surveys in a minimum of 2 acute and 2 community NHS Trusts (2,000 hospital and 6,000 community patients) therefore an approximate number of 8,000 patients is planned for the PU prevalence audit.

It is estimated that the prevalence of PUs in hospital patients is 10% and in community patients 5%; 30% of these are patients with Grade 2-U PUs and we estimate that 25-50% of these patients will report localised PU pain; the remaining 70% of patients have a Grade 1 PU, and we estimate that between 5-20% of these patients will report PU pain[3,5]. Of the remaining 90% hospital and 95% community patients without PUs, we estimate that localised skin pain may be reported in 2.5-5% of patients. Based on these assumptions, we estimate that between 259 and 555 patients will report localised PU-related pain (see Table 2, over page), i.e. that 3-7% of patients will report localised skin pain on a pressure area.

A sample of 8,000 patients will enable us to estimate a pain prevalence of 3% to within ± 0.38% (n = 7,742) and a pain prevalence of 7% to within ± 0.56% (n = 7,975).

8 Statistical Analysis

8.1 General Considerations

Statistical analysis is the responsibility of the CTRU Statistician. The analysis plan outlined in this section will be reviewed and a final statistical analysis plan will be written before any data summaries or analyses are performed. The analysis plan will be written in accordance with current CTRU Standard Operating Procedures (SOPs) and will be finalised and agreed by the following people: Trial Statistician, Supervising Statistician, Chief Investigator, Senior Trial Manager, and Programme Manager. Any changes to the final analysis plan and reasons for change will be documented.

Table 2: Estimated number of patients with PU pain

Setting	Pressure ulcer (PU) status		Pain	
			n	%
Hospital (n = 2,000)	No PU (90%; n = 1,800)		45-90	2.5-5%
	PU (10%; n = 200)	Grade 1 (70%; n = 140)	14-42	10-30%
		Grade 2-4 (30%; n = 60)	15-30	25-50%
Community (n = 6,000)	No PU (95%; n = 5,700)		142-285	2.5-5%
	PU (5%; n = 300)	Grade 1 (70%; n = 210)	21-63	10-30%
		Grade 2-4 (30%; n = 90)	22-45	25-50%

8.2 Routine PU Prevalence Audit

Standard PU prevalence results and analysis as per usual practice will be provided to each participating centre and will include the overall prevalence of PU by grade, risk profile, age, department and gender.

8.3 PU Pain Prevalence Audit

The proportion of patients reporting localised skin pain will be summarised for the overall population and for each acute/community Trust.

8.4 Full Pain and Skin Assessment

For those patients reporting pain and undergoing further assessment, the intensity and type of pain (whether neuropathic or nociceptive) will be summarised using means and standard deviations, or percentages and 95% confidence intervals, by skin site (e.g. sacrum, buttocks, heels) and skin classification at that site.

11.2 Ethical Considerations

This project will assess all hospital and community nursing patients including those with PUs and therefore will include elderly and highly dependent patients considered as vulnerable. Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and include piggy-backing the pain prevalence onto routine PU prevalence surveys and the use of local staff including experienced nurses and members of the Trust TVT to assess patients. The study will be submitted to and be approved by a Research Ethics Committee (REC) prior to identifying eligible patients. The CTRU will provide the REC with a copy of the final protocol, patient information leaflets, consent forms, and all other relevant study documentation.

16 References

(4) European Pressure Ulcer Advisory Panel (EPUAP) Pressure Ulcer Treatment Guidelines (1998). http://www.epuap.org/gltreatment.html (accessed 23/01/2008).

(8) Royal College of Physicians, British Geriatrics Society and British Pain Society. The assessment of pain in older people: national guidelines. Concise guidance to good practice series, No 8. London: RCP, 2007.

(9) Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations. The Journal of Pain 2008; 9(2): 105-121.

(10) Bennett M. The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and signs. Pain 2001; 92(1-2): 147-157.

(11) Briggs M, Bennett MI, Closs SJ, Cocks K. Painful leg ulceration: a prospective, longitudinal cohort study. Wound Repair and Regereration 2007; 15(2): 186-191.

Appendix 2: The LANSS Pain Scale

Leeds Assessment of Neuropathic Symptoms and Signs[10] (with adaptations)[11]

[NB: The LANSS scale was collected however the scale is omitted due to copyright. The LANSS scale can be obtained from: Bennett M. The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and signs. Pain 2001; 92(1-2): 147-157].

Appendix 4 Pain prevalence study patient information leaflet

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Participant Information Leaflet and Consent Form

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Prevalence - Prevalence of localised pressure ulcer related pain

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward/community nurse if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

The purpose of this study is to see how many people who are in hospital or being treated by community nurses have pain, soreness or discomfort in one of the areas where pressure ulcers, or bed sores, commonly develop (like the lower back, buttocks, and heels). This information will be used by healthcare practitioners to improve assessment and treatment of localised skin and pressure ulcer pain.

Why have I been invited to participate?

This study is looking at people like you who are in hospital or under the care of community nursing services and who have pain in an area that may experience pressure from being in bed or a chair. Participants from many hospitals and within the community will be asked to take part.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part you will be asked to sign the consent form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, a family member, or member of your healthcare team. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

What will happen to me if I take part?

If you agree to take part in the study, a nurse will ask you a few extra questions, assess your skin sensation, and check your skin (or pressure sore if you have one). This single assessment will take place in your own home or on the hospital ward you are on at a time convenient for you.

What are the possible disadvantages and risks of taking part?

This study is a one-off assessment which should take about an hour. We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time for taking part. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the information from this study will help to improve awareness and treatment of pressure ulcer related pain in the future.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with your healthcare practitioner or other healthcare professional who will do their best to answer your

questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. In the unlikely event that you think you have been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from your healthcare practitioner.

Will my taking part be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point during or following completion of the study without giving a reason. A decision to withdraw at any time will not affect the standard of care you receive, nor will it affect your relationships with your doctors and nurses in any way.

Will my taking part in this study be kept confidential?

If you decide to participate in the study, the information collected about you during the course of the study will be anonymised and kept strictly confidential. This information will handled, processed, stored, and destructed in accordance to the Data Protection Act 1998. The study team have a duty of confidentiality to you and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your medical records, will have your name and address removed from it. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible to members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs may include reports, presentations, and papers (published in a medical journal), and further healthcare and/or medical research, but these will not be traceable to specific individuals.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds Central Research Ethics Committee (reference 09/H1313/14).

Further information and contact details

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org

Your contact telephone numbers:

(*to include local PI*) ……..

……

Patient Study Number:	DOB:
Principal Investigator:	Version: 3.0

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PATIENT CONSENT FORM

Where witnessed consent is required please use the Witnessed Consent Form

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Prevalence - Prevalence of localised pressure ulcer related pain

	Patient initial after each question
1. I confirm that I have read and understand the information sheet dated 18/01/2010 (version 3.0) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust Teams and the Sponsor, where it is relevant to my study participation. I give permission for these individuals to have access to my records.	.....
4. I agree to take part in the study.	.....

_____ _____ _____

Name of Patient Date Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Person taking consent Date Signature

(1 copy for patient; 1 for patient records; original stored in Investigator Site File)

Appendix 5 Pain prevalence study witnessed consent form

Patient Study Number:	DOB:
Principal Investigator:	Version: 3.0

[Delete this line, then print on Trust headed paper]

WITNESSED CONSENT FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Prevalence - Prevalence of localised pressure ulcer related pain

	Witness initial after each question on behalf of the patient
1. I confirm that I have read and understand the information sheet dated 18/01/2010 (version 3.0) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust Teams and the Sponsor, where it is relevant to my study participation. I give permission for these individuals to have access to my records.	.....
4. I agree to take part in the study.	.....

_____

Name of Patient

Witness statement

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

_____	_____	_____
Name of Witness	Date	Signature

Research person taking Consent

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

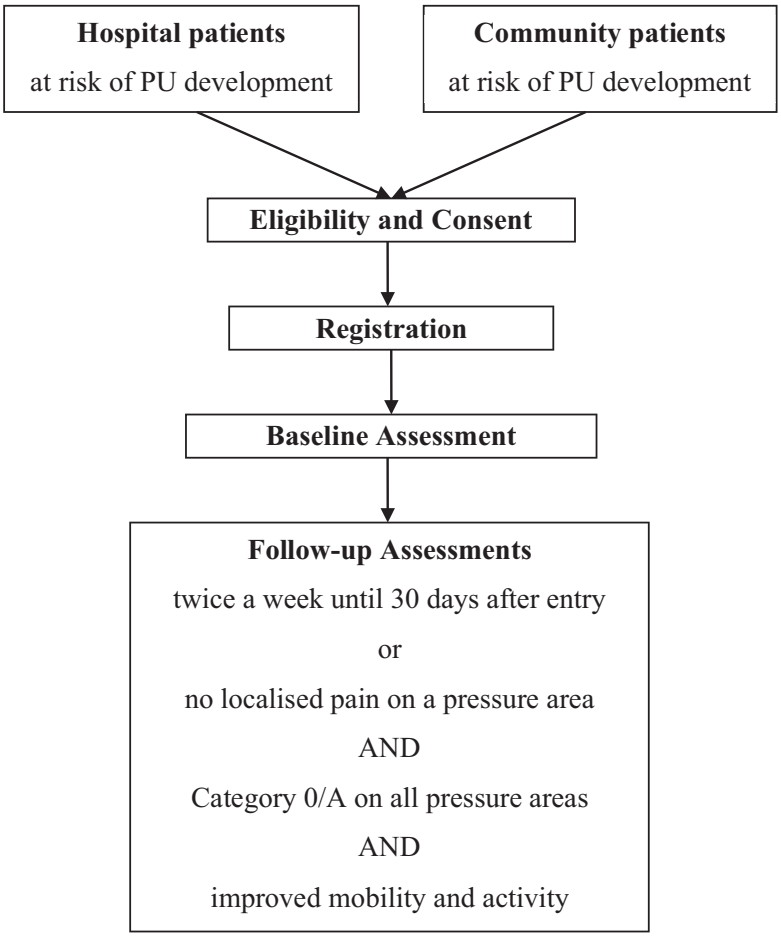
_____	_____	_____
Name of person taking consent	Date	Signature

(1 copy for patient; 1 for patient records; original stored in Investigator Site File)

Appendix 6 Pain cohort study reduced format protocol

NB: This study protocol (version 4, dated 18 Jan 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to serious adverse events, data monitoring, quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, and publication policy are available upon request

3 Flow diagram/trial summary



5 Aim and objectives

The main aim of this study is to explore the role of pain as an early predictor of Category 2 PU development (see Table 1).

Objectives are:

1. To assess whether the presence/absence of localised skin pain is a predictor of ≥ Category 2 pressure ulcer development.
2. To explore the relationship between skin classification category and reported pain and pain severity.
3. To identify variables which are independently predictive of ≥ Category 2 pressure ulcer development.

Table 1. NPUAP/EPUAP Pressure Ulcer Classification System[6]. For the purpose of the research the classification has been adapted to enable grading of normal skin and unstageable pressure ulcers.

Category	Description
Category 0 Healthy intact skin	No skin changes.
Category A Alterations to intact skin	Alterations to intact skin.
Category 1 Non-blanchable erythema of intact skin	Intact skin with non-blanchable erythema of a localised area usually over a bony prominence. Discolouration of the skin, warmth, oedema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.
Category 2 Partial thickness skin loss or blister	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum or sero-sanginous-filled blister.
Category 3 Full thickness skin loss	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are *not* exposed. Some slough may be present. *May* include undermining and tunnelling.
Category 4 Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. *Often* includes undermining or tunnelling.
Category U Unstageable	Full thickness skin loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, grey, green, or brown) and/or eschar (tan, brown, or black) in the wound bed.

6 Methods

6.1 Design

We plan to undertake a prospective cohort study with 30 days follow-up, in acute and community NHS Trusts involving 632 patients at high-risk of PU development.

6.2 Eligibility

6.2.1 Acute Hospital Patients Inclusion Criteria

1. acute vascular, orthopaedic, medical or care of the elderly admission
2. aged ≥ 18 years
3. have an expected total length of stay of 5 or more days
4. at high risk of PU development due to one or more of the following:
    a. bedfast/chairfast AND completely immobile/very limited mobility (see Appendix 2)
    b. localised skin pain on any pressure area skin site (see section 6.2.4)
    c. Category 1 PU on any pressure area skin site (see Table 1)
5. give their written, informed consent to participate
6. expected to be able to comply with follow-up schedule.

6.2.2 Community Patients Inclusion Criteria

1. evidence of acute illness through one or more of the following:
    a. recent hospital discharge to home/intermediate/community care/hospice/specialist palliative care
    b. existing community nursing patient with deterioration in overall condition or onset of acute illness
    c. new referral to community nursing due to acute illness, deterioration in existing condition, or care package breakdown.
2. aged ≥ 18 years
3. at high risk of PU development due to one or more of the following:
    a. bedfast/chairfast AND completely immobile/very limited mobility (see Appendix 2)
    b. localised skin pain on any pressure area skin site (see section 6.2.4)
    c. Category 1 PU on any pressure area skin site (see Table 1)
4. give their written, informed consent to participate

5. expected to be able to comply with follow-up schedule.

6.2.3 Exclusion Criteria (Acute Hospital & Community Patients)

1. Obstetrics, paediatrics, day case surgery, and psychiatric patients in both acute and community settings
2. Unable to provide written, informed consent
3. Unable to comply with follow-up assessment schedule
4. Deemed by the attending healthcare professional to be too unwell to be approached and/or complete the study assessment schedule
5. Unable to report the presence/absence of pain (e.g. unconscious)
6. Patients with two or more ≥ Category 2 PUs on any key pressure area skin sites (sacrum, buttocks, heels, hips; see Table 1).

6.2.4 Pain Questions

To determine if patients have localised skin pain on any pressure area skin site they will be asked the following two questions by a member of the research team. Patients will be eligible for inclusion under this criteria if they answer 'yes' to both questions.

1. At any time, do you get pain, soreness, or discomfort on a pressure area? *Prompt – back, bottom, hips, elbows, heels, or other as applicable to the patient?*
2. Do you think this is related to either: your pressure sore; laying in bed for a long time; sitting for a long time (*as appropriate*)?

6.3 Endpoints

The classification scale is adapted from the international classification scales[5] in order to meet practical data collection requirements for the purpose of research (Table 1). Specifically, Category 0 (no skin changes) is included to clearly distinguish skin assessment of normal skin from missing data and Category A (alterations to intact skin) is included as alterations to intact skin have been identified as independently predictive of Category 2 PU outcome[4,7].

The primary endpoint is defined as the development of a new Category ≥2 PU after registration and before study completion.

6.3.1 Follow-up

In the patient population recruited to the study we anticipate that hospital patients will be discharged to community settings and community patients may be admitted to hospital. Patients will continue follow-up across healthcare settings, with ethics and R&D approval sought in adjacent NHS Trusts to facilitate this. Patient follow-up will be discontinued when the patient fulfils one of the following criteria:

1. 30 days from registration OR
2. no longer at high risk because:
    a. no localised skin pain on any pressure area skin site (see section 6.2.4) AND
    b. Category 0/A on all pressure area skin sites AND
    c. improved mobility and activity (score of 3 or 4 on both the activity and mobility scores of the Braden Scale[8] Appendix 2) OR
3. death.

6.4 Recruitment and consent

Where eligibility is indicated by the attending clinical team, patients will be flagged to a member of the Trust Tissue Viability Team (TVT; Tissue Viability Nurse Consultant/Specialist/Research Nurse). The attending clinical team may or may not already include a member of the Trust TVT. A full verbal explanation of the study Patient Information Leaflet will be provided by the attending clinical staff or a member of the TVT for the patient to consider. This will include detailed information about the rationale, design, and personal implications of the study. Following information provision, patients will have as long as they need to consider participation and will be given the opportunity to discuss the study with their family and other healthcare professionals before they are asked whether they would be willing to take part in the study.

Assenting patients will then be invited to provide informed, written consent. A record of the consent process detailing the date of consent will be kept in the patient healthcare records. Assessment of eligibility and informed consent will usually be undertaken by a member of the TVT. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment.

Should the patient be capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member or friend of the patient, or another member of the patient's healthcare team who is not directly involved in the research study.

The original consent form will be retained in the Investigator Site File, a copy of the consent will be given to the patient and a second copy filed in the patient healthcare notes.

7 Screening and registration

7.1 Screening

Participating research sites will be required to complete a log of all patients screened for eligibility. Anonymised information will be collected including:

- age
- gender
- ethnicity
- whether the patient is registered or not registered

Screened patients who are not registered either because they are ineligible or because they decline participation will also have the following information recorded:

- the reason not eligible for study participation OR
- the reason eligible but declined

This anonymised information will be returned on a monthly basis to the Clinical Trials Research Unit (CTRU).

7.2 Registration

Screened patients who are both eligible for study participation and provide written informed consent will be registered. Informed consent for entry into the study must be obtained prior to registration. Following confirmation of written informed consent and eligibility patients will be registered into the study by an authorised member of staff at the study research site.

Registration will be performed centrally using the CTRU automated 24-hour telephone registration system. Authorisation codes and PINs, provided by the CTRU, will be required to access the registration system.

The following information will be required at registration:

- Patient details, including initials, gender and date of birth
- Site code for research site
- Name of person making the registration
- Confirmation of eligibility
- Confirmation of written informed consent

Direct line for registration +44 (0)113 343 8278

8 Assessments and data collection

Assessments will be undertaken by members of the TVT as follows:

- Baseline assessment (after consent but prior to registration)
- Follow-up assessments twice weekly for 30 days or until study completion (see section 6.3.1).

8.1 Baseline Assessment

Authorised healthcare practitioners will record baseline information including:

8.2 Baseline demographics

- Patient's NHS ID
- Patient's Hospital/Trust number (if applicable)
- Name of NHS Trust
- NHS Facility/Service name (name of hospital/intermediate community nursing team)
- Type of admission/referral
- *Hospital patients only* - speciality (vascular/orthopaedic/medical-elderly)
- Date of admission to hospital/community referral
- Initials
- Date of birth
- Gender

- Ethnicity
- Confirmation General Practitioner (GP) letter sent
- Confirmation responsible healthcare professional letter sent (if applicable)

8.3 Personal data (to be retained in the site file and not returned to the CTRU)

- Patient name
- Patient location e.g. hospital/intermediate care/home
- *Community patients/hospital discharge patients only:*
- Patient address and telephone number
- GP name and address
- District Nurse name and address
- Other responsible healthcare professional (e.g. Specialist or Consultant Nurse) name and address
- *Hospital/hospitalised patients only:*
- Ward
- Responsible healthcare professional (e.g. Consultant Physician or Surgeon, a Specialist or Consultant Nurse) name and address

8.4 Risk factors and population characteristics

  - Skin assessment (sacrum, buttocks, heels, hips and other) using the skin classification scale (Table 1)
  - Braden Scale[8] subscales (Appendix 2)
  - Pain assessment (see section 8.2.1, Appendix 3)
- Diabetic status
- Other chronic wounds (type and location)
- Nutritional status
- Analgesic use
- Pressure ulcer prevention and treatment interventions

8.5 Follow-up assessments (twice-weekly up to 30 days)

- Skin assessment (sacrum, buttocks, heels, hips and other) using the skin classification scale (Table 1)
- Mobility/activity score using Braden Scale[8] (Appendix 2)

- Pain assessment (see section 8.2.1, Appendix 3)
- Analgesic use
- Pressure ulcer prevention and treatment interventions
- Serious Adverse Events (see section 11)
- Confirmation of continued eligibility (see section 6.3.1)

8.5.1 Pain Assessment

Patients will be asked the two screening questions for all pressure areas (see section 6.2.4) at baseline. Where patients answer yes to both screening questions at baseline these sites will be assessed using a numerical rating scale[9,10] for pain intensity (for most severe pain over the past week). In addition, duration of pain will be recorded.

Up to two Category 0-1 skin areas will be assessed using the Leeds Assessment Neuropathic Symptoms and Signs (LANSS) Pain Scale[11,12] (Appendix 3). The LANSS consists of a brief clinical assessment and is easy to score in a clinical setting. The questionnaire contains 5 symptom items and 2 clinical sensory testing items associated with neuropathic pain. The LANSS Scale is a clinically validated tool which allows assessment of neuropathic and inflammatory pain, and has been used in a wide variety of clinical settings[12]. The two sites assessed using the LANSS will include the most painful skin site located on the torso (i.e. sacrum, buttocks, ischial tuberosities, hips) and the most painful site located on a limb (i.e. heels, elbows). In addition, where a patient has a ≥ Category 2 PU at baseline, this will be assessed using the LANSS.

At follow-up patients will be asked the two screening questions for all pressure areas (see section 6.2.4) at each visit. Where pain at the skin site is reported intensity will be assessed using the numerical rating scale[9,10]. For the skin sites where the LANSS assessment was undertaken at baseline, this will be repeated at visits 4 and 8, until either study conclusion or when pain is no longer present at that skin site (i.e. one of the two screening questions is ‘no’).

All anonymised data will be returned to CTRU for data processing.

9 Statistical considerations

9.1 Sample size

Our aim in this study is to assess whether the presence of localised skin pain is predictive of whether or not a patient develops a new PU of Category 2 or above, after adjusting for the effects of other known risk factors which are: age, diabetes, nutritional status, presence of chronic wound on any skin site, presence of skin alterations, Category 1 ulcer on any site, and patient setting (hospital elective, hospital acute, community). As a patient's perception of pain is likely to be affected by the use of analgesics or other forms of pain relief, we will collect this data and include analgesic use as a covariate in the model.

For risk factor studies using logistic regression it is recommended that at least 10 patients with the event of interest are needed for reliable estimation of effects[13]. A model including 9 factors (pain, the seven pre-specified risk factors, and analgesic use) would therefore require a minimum of 90 patients to develop a new pressure ulcer of Category 2 or above. Previous research[7,14] suggests that approximately 15% of patients will develop a new PU of Category 2 or above within 30 days of entering the study. Based on this assumption and allowing for potential loss to follow up of 5% will require 632 patients to be recruited to this study.

Table 2 shows the largest difference in PU incidence that can be detected with a minimum of 80% power for patients with 10 or 20% pain at study entry with estimated PU event rates in the patients without pain of 10 and 15% and assumes that patients with pain at study entry are more likely to develop a new ulcer than those without pain at entry.

Table 2. Largest difference in PU incidence with 80% power.

Total	Baseline pain		PU incidence			PU incidence		
	With pain N (%)	Without pain N (%)	With pain	Without pain	Diff	With pain	Without pain	Diff
632	64 (10%)	568 (90%)	24.4%	10.0%	14.4%	30.9%	10.0%	15.9%
			OR 2.988 (1.594, 5.603)			OR 2.548 (1.432, 4.533)		
632	127 (20%)	505 (80%)	20.2%	15.0%	10.2%	26.5%	15.0%	11.5%
			OR 2.292 (1.363, 3.851)			OR 2.064 (1.300, 3.277)		

If we recruit 632 patients with 64 (10%) of them having pain on study entry this will allow us to detect a statistically significant difference ($p<0.05$) of 14.4% between those with and without pain using a chi-squared test (80% power, 5% significance) if 10% of patients without pain and 24.4% of those with pain develop a new PU within the 30-day follow up period, corresponding to an odds ratio (OR) of 2.988 with 95% CI (1.594, 5.603)

As this is an exploratory study and there is uncertainty around the assumption made to estimate sample size, the proportion of patients with pain at baseline and the incidence of PU development will be monitored by the statistical team throughout the study, and implications for sample size flagged to the Project Team.

10 Statistical analyses

10.1 General Considerations

Statistical analysis is the responsibility of the CTRU Statistician. The analysis plan outlined in this section will be reviewed and a final statistical analysis plan will be written before any data summaries or analyses are performed. The analysis plan will be written in accordance with current CTRU Standard Operating Procedures and will be finalised and agreed by the following people: the Trial Statistician and Supervising Statistician, the Chief Investigator, Senior Trial Manager, and Programme Manager. Any changes to the final analysis plan and reasons for change will be documented.

10.2 Primary Analysis

Logistic regression analysis will be used to assess the relationship between the presence or absence of localised pain at any skin site and the development of a PU of Category 2 or above, using univariate analysis, and also multivariable analysis accounting for the covariates (age, diabetes, skin alterations, Category 1 ulcer on any site, patient setting, and analgesic use). The odds ratios, 95% confidence intervals and p-values from all analyses will be presented. All primary analysis will be performed on a per-patient basis. An additional analysis will explore the relationship between pain at a specific skin site and the development of a new PU on the same site using multilevel logistic regression modelling to account for the clustering of skin sites within a patient.

10.3 Secondary Analysis

Additional analyses will also be undertaken to:

i) Explore the relationship between skin classification category and reported pain by summarising the presence/absence and severity of pain for each of the skin classification categories

ii) Identify variables which are independent predictors of Category 2 PU development. This will use logistic regression modelling as per the primary analysis but will use forwards and backwards selection modelling to identify the most suitable set of covariates for predicting PU development

iii) Assess the relationship between changes in pain over time and the time to PU development by treating pain as a time-dependent covariate in a Cox proportional hazards model both in a univariate analysis and after adjusting for the same covariates used in the primary analysis.

13.2 Ethical considerations

This study will include elderly and highly dependent patients considered as vulnerable. Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and the use of local staff including experienced clinical nurses, that is, members of the local TVT to assess patients.

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000. Informed written consent will be obtained prior to registration into the study. The right of a patient to refuse participation without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment. The study will be submitted to and approved by a main Research Ethics Committee (main REC) and the appropriate Site Specific Assessor for each participating centre prior to entering patients into the study. The CTRU will provide the main REC with a copy of the final protocol, patient information sheets, consent forms and all other relevant study documentation.

18 References

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(8) Copyright Barbara Braden and Nancy Bergstrom, 1988. Reprinted with permission. Permission should be sought to use this tool at www.bradenscale.com

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(13) Machin D, Campbell S. Design of Studies for Medical Research. Wiley; 2005.

(14) Nixon J, Cranny G, Bond S. Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study. International Journal of Nursing Studies 2007; 44(5): 665-663.

Appendix 2: The Braden Scale

[NB: Data for the Braden scale was collected however the scale is omitted due to copyright. The Braden scale can be requested from URL: http://bradenscale.com/].

Appendix 3: The LANSS Pain Scale

Leeds Assessment of Neuropathic Symptoms and Signs[10] (with adaptations)[11]

[NB: The LANSS scale was collected however the scale is omitted due to copyright. The LANSS scale can be obtained from: Bennett M. The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and signs. Pain 2001; 92(1-2): 147-157].

Appendix 7 Pain cohort study patient information leaflet

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PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Cohort - Exploring the role of pain as an early predictor of Category 2 pressure ulcers

PATIENT INFORMATION SHEET

A large-print version of this sheet is available on request.

You have been invited to take part in a research Project. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with your relatives or carers if you wish. Ask us if anything is unclear, or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

The purpose of this study is to explore if reports of patients pressure area pain, can help healthcare professionals predict which patients will develop a pressure ulcer (commonly known as a bed sore). The information gathered will be used to improve assessment and treatment of skin and pressure ulcer pain.

Why have I been chosen?

This study is looking at people like you who are in hospital or under the care of community nursing services, participants from many hospitals and within the community will be asked to take part. You may have pain in an area that may experience pressure from being in bed or a chair.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part you will be asked to sign the consent form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, a family member, or member of your healthcare team. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

What will happen to me if I take part?

If you agree to take part in the study, a nurse will ask you some questions relating to your skin and pressure or rubbing, assess your skin sensation, and check your skin (or pressure sore if you have one) in the areas you have pain or discomfort. This assessment will be done when you enter the study, and will be repeated twice a week for 30 days (a total of 8 follow-up assessments). The assessments will take about 30 minutes and will take place in your own home or on the hospital ward you are on at a time convenient for you.

If you are in hospital and you are discharged before the end of 30 days, we will ask you if we can have your contact details so we can follow you up until the end of the 30 days. These will be confidentially destroyed at the end of the study.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time for taking part. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the information from this study will help to improve awareness and treatment of pressure ulcer related pain in the future.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with your healthcare practitioner or other healthcare professional who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. In the unlikely event that you think you have been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from your healthcare practitioner.

Will my taking part be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence.

Involvement of your General Practitioner (GP) / Other Healthcare Practitioner

Your GP will be informed that you are participating in this study. If you are under the care of a Hospital Consultant, Specialist or District Nurse, they will also be informed of your participation.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point during or following completion of the study without giving a reason. A decision to

withdraw at any time will not affect the standard of care you receive, nor will it affect your relationship with the medical and nursing team who are looking after you.

Will my taking part in this study be kept confidential?

If you decide to participate in the study, the information collected about you during the course of the study will be anonymised and kept strictly confidential. This information will handled, processed, stored, and destructed in accordance to the Data Protection Act 1998. The study team have a duty of confidentiality to you and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained you're your medical records, will have your name and address removed from it. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible to members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs may include reports, presentations, and papers (published in a medical journal), and further healthcare and/or medical research, but these will not be traceable to specific individuals.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds Central Research Ethics Committee (reference 09/H1313/32).

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified in any report or publication. If you would like to

obtain a copy of the published results, please ask your local contact person (see contact details below).

Further information and contact details

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org

Your contact telephone numbers:

(*to include local collaborator*)……..

…….

Appendix 8 Pain cohort study consent forms

Patient Study Number:	Patient Initials:
Patient DOB:	Site ID:
Principal Investigator:	Version: 4.0

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PATIENT CONSENT FORM

Where witnessed consent is required please use the Witnessed Consent Form

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Cohort - Exploring the role of pain as an early predictor of Category 2 pressure ulcers

	Patient initial after each question
1. I confirm that I have read and understand the information sheet dated 18/01/2010 (version 4.0) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust Teams and the University of Leeds, where it is relevant to my study participation. I give permission for these individuals to have access to my records.	.....
4. I consent to the storage including paper and electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. This information will be confidentially destroyed at the end of the study.	.....
5. I agree that my GP and hospital consultant/Specialist or District nurse (where applicable) will be notified of my participation in this study.	.....
6. I agree to take part in the study.	.....

Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Name of Person taking consent	Date	Signature

(1 copy for patient; 1 for patient records; original stored in Investigator Site File)

Patient Study Number:	Patient Initials:
Patient DOB:	Site ID:
Principal Investigator:	Version: 4.0

[Delete this line, then print on Trust headed paper]

WITNESSED CONSENT FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Cohort - Exploring the role of pain as an early predictor of Category 2 pressure ulcers

	Witness initial after each question on behalf of the patient
1. I confirm that I have read and understand the information sheet dated 18/01/2010 (version 4.0) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust Teams and the University of Leeds, where it is relevant to my study participation. I give permission for these individuals to have access to my records.	.....
4. I consent to the storage including paper and electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. This information will be confidentially destroyed at the end of the study.	.....
5. I agree that my GP and hospital consultant/Specialist or District nurse (where applicable) will be notified of my participation in this study.	.....
6. I agree to take part in the study.	.....

_____

Name of Patient

Witness statement

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

_____	_____	_____
Name of Witness	Date	Signature

Research person taking consent

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____	_____	_____
Name of Person taking consent	Date	Signature

(1 copy for patient; 1 for patient records; original stored in Investigator Site File)

Appendix 9 Cross-tabulations of explanatory variables

TABLE 92 Cross-tabulation of the presence of skin alterations and the presence of a category 1 pressure ulcer at baseline

	Skin alterations, *n* (%)		
Category 1 pressure ulcer	Yes	No	Total, *n* (%)
Yes	170 (28.2)	120 (19.9)	290 (48.2)
No	203 (33.7)	109 (18.1)	312 (51.8)
Total	373 (62.0)	229 (38.0)	602 (100.0)

TABLE 93 Cross-tabulation of the presence of pain on a healthy, altered or category 1 skin site and the presence of a category 1 pressure ulcer at baseline

	Pain on a category 0, 1 or A skin site, *n* (%)		
Category 1 pressure ulcer	Yes	No	Total, *n* (%)
Yes	247 (41.0)	43 (7.1)	290 (48.2)
No	217 (36.0)	95 (15.8)	312 (51.8)
Total	464 (77.1)	138 (22.9)	602 (100.0)

TABLE 94 Cross-tabulation of the presence of a category 2 pressure ulcer and the presence of a category 1 pressure ulcer at baseline

	Category 2 pressure ulcer, *n* (%)		
Category 1 pressure ulcer	Yes	No	Total, *n* (%)
Yes	76 (12.6)	214 (35.5)	290 (48.2)
No	88 (14.6)	224 (37.2)	312 (51.8)
Total	164 (27.2)	438 (72.8)	602 (100.0)

TABLE 95 Cross-tabulation of Braden activity score with the presence of a category 1 pressure ulcer at baseline

	Braden activity score, *n* (%)				
Category 1 pressure ulcer	Bedfast	Chairfast	Walks occasionally	Walks frequently	Total, *n* (%)
Yes	51 (8.5)	145 (24.1)	88 (14.6)	6 (1.0)	290 (48.2)
No	53 (8.8)	168 (27.9)	69 (11.5)	22 (3.7)	312 (51.8)
Total	104 (17.3)	313 (52.0)	157 (26.1)	28 (4.7)	602 (100.0)

TABLE 96 Cross-tabulation of the presence of a chronic wound with the presence of a category 1 pressure ulcer at baseline

	Chronic wound, *n* (%)		
Category 1 pressure ulcer	Yes	No	Total, *n* (%)
Yes	72 (12.0)	218 (36.2)	290 (48.2)
No	55 (9.1)	257 (42.7)	312 (51.8)
Total	127 (21.1)	475 (78.9)	602 (100.0)

TABLE 97 Cross-tabulation of the presence of pain at a category 0, 1 or A skin site with the presence of skin alterations at baseline

	Pain on a category 0, 1 or A skin site, *n* (%)		
Skin alterations	Yes	No	Total, *n* (%)
Yes	301 (50.0)	72 (12.0)	373 (62.0)
No	163 (27.1)	66 (11.0)	229 (38.0)
Total	464 (77.1)	138 (22.9)	602 (100.0)

TABLE 98 Cross-tabulation of the presence of a category 2 pressure ulcer at baseline with the presence of skin alterations at baseline

	Category 2 pressure ulcer, *n* (%)		
Skin alterations	Yes	No	Total, *n* (%)
Yes	99 (16.4)	274 (45.5)	373 (62.0)
No	65 (10.8)	164 (27.2)	229 (38.0)
Total	164 (27.2)	438 (72.8)	602 (100.0)

TABLE 99 Cross-tabulation of Braden activity score with the presence of skin alterations at baseline

	Braden activity score, *n* (%)				
Skin alterations	Bedfast	Chairfast	Walks occasionally	Walks frequently	Total, *n* (%)
Yes	55 (9.1)	196 (32.6)	99 (16.4)	23 (3.8)	373 (62.0)
No	49 (8.1)	117 (19.4)	58 (9.6)	5 (0.8)	229 (38.0)
Total	104 (17.3)	313 (52.0)	157 (26.1)	28 (4.7)	602 (100.0)

TABLE 100 Cross-tabulation of the presence of chronic wounds with the presence of skin alterations at baseline

Skin alterations	Chronic wound, *n* (%)		Total, *n* (%)
	Yes	No	
Yes	87 (14.5)	286 (47.5)	373 (62.0)
No	40 (6.6)	189 (31.4)	229 (38.0)
Total	127 (21.1)	475 (78.9)	602 (100.0)

TABLE 101 Cross-tabulation of the presence of pain on a category 0, 1 or A skin site with the presence of a category 2 ulcer at baseline

Pain on a category 0, 1 or A skin site	Category 2 pressure ulcer, *n* (%)		Total, *n* (%)
	Yes	No	
Yes	103 (17.1)	361 (60.0)	464 (77.1)
No	61 (10.1)	77 (12.8)	138 (22.9)
Total	164 (27.2)	438 (72.8)	602 (100.0)

TABLE 102 Cross-tabulation of Braden activity score with the presence of pain on a healthy, altered or category 1 skin site at baseline

Pain on a category 0, 1 or A skin site	Braden activity score, *n* (%)				Total, *n* (%)
	Bedfast	Chairfast	Walks occasionally	Walks frequently	
Yes	71 (11.8)	239 (39.7)	128 (21.3)	26 (4.3)	464 (77.1)
No	33 (5.5)	74 (12.3)	29 (4.8)	2 (0.3)	138 (22.9)
Total	104 (17.3)	313 (52.0)	157 (26.1)	28 (4.7)	602 (100.0)

TABLE 103 Cross-tabulation of the presence of chronic wounds with the presence of pain at a category 0, 1 or A skin site at baseline

Pain on a category 0, 1 or A skin site	Chronic wound, *n* (%)		Total, *n* (%)
	Yes	No	
Yes	105 (17.4)	359 (59.6)	464 (77.1)
No	22 (3.7)	116 (19.3)	138 (22.9)
Total	127 (21.1)	475 (78.9)	602 (100.0%)

TABLE 104 Cross-tabulation of Braden activity score with the presence of a category 2 pressure ulcer at baseline

	Braden activity score, *n* (%)				
Category 2 pressure ulcer	Bedfast	Chairfast	Walks occasionally	Walks frequently	Total
Yes	30 (5.0)	78 (13.0)	50 (8.3)	6 (1.0)	164 (27.2)
No	74 (12.3)	235 (39.0)	107 (17.8)	22 (3.7)	438 (72.8)
Total	104 (17.3)	313 (52.0)	157 (26.1)	28 (4.7)	602 (100.0)

TABLE 105 Cross-tabulation of an existing category 2 pressure ulcer with the presence of chronic wounds at baseline

	Chronic wound, *n* (%)		
Category 2 pressure ulcer	Yes	No	Total, *n* (%)
Yes	39 (6.5)	125 (20.8)	164 (27.2)
No	88 (14.6)	350 (58.1)	438 (72.8)
Total	127 (21.1)	475 (78.9)	602 (100.0)

TABLE 106 Cross-tabulation of Braden activity score with the presence of chronic wounds at baseline

	Chronic wound, *n* (%)		
Braden activity	Yes	No	Total, *n* (%)
Bedfast	15 (2.5)	89 (14.8)	104 (17.3)
Chairfast	63 (10.5)	250 (41.5)	313 (52.0)
Walks occasionally	36 (6.0)	121 (20.1)	157 (26.1)
Walks frequently	13 (2.2)	15 (2.5)	28 (4.7)
Total	127 (21.1)	475 (78.9)	602 (100.0)

Appendix 10 Severe pressure ulcer study reduced format protocol

NB: This study protocol (version 3, dated 4 Feb 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to confidentiality, archiving, statement of indemnity, study organisational structure, publication policy, and dissemination are available upon request.

4 AIMS

The aim of the research study is to identify the unexplained reasons which may contribute to the development of severe pressure ulcers, using innovative methods of investigation (Vaughan, 1996; Perrow, 1984; Waring et al., 2006; Pawson, 2006; 2008).

5 STUDY DESIGN

5.1 Brief Overview

Following a similar approach to a public Inquiry (e.g. the tragic case of Victoria Climbié or the Bristol heart babies inquiry) the study will use a retrospective case study approach (Ragin, 2000). This involves examining patients with severe (Category 3 and 4) pressure ulcers, starting at the point where they have already developed. This study will seek to explain which *non-clinical* influences could lead to a patient developing a Category 3 and 4 pressure ulcer.

5.2.1 Stage 1

This first stage will involve identifying one person who presents unexpectedly with a Category 3 or 4 pressure ulcer according to the TVT (see Nixon et al, 2007). It may be that the person has few known clinical risk factors for developing a severe pressure ulcer, yet develops one. The reason for choosing such a patient is that multiple clinical risks of developing a severe pressure ulcer may mask any underlying non-clinical influences. Therefore the aim is to keep clinical risk factors to a minimum at this stage.

The overall purpose is to create a coherent account of what happens during the development of a severe (Category 3 or 4) pressure ulcer. By ‘coherent account’ we mean one which makes the best sense of available, yet relevant evidence, similar in nature to the process

police use when they build evidence against a suspect. We will sift through the accumulated evidence (environmental, individual and so forth), and look for other 'clues' about what may have a bearing on the person's developing a Category 3 and 4 pressure ulcer. This will involve retrospective searching of a person's care 'pathway', firstly talking to a patient about his or her experience of care from the start of the pressure ulcer, and searching all relevant healthcare documentation, to start to produce a coherent account.

We will also talk to other people involved in a patient's care pathway, such as informal and professional carers, nurses, and other relevant people, gaining their personal experience of the development of the severe pressure ulcer. This further information will help consolidate the coherence account as more evidence is uncovered. A timeline of events and a narrative chronology will be used to help with searching, and provide a basis to compare further patient experiences. This stage will conclude with *tentative hypotheses* about non-clinical explanations, such as we might find that a patient moving around different services seems to have an impact on their developing a Category 3 or 4 pressure ulcer, and this would then be a tentative hypothesis. We will provide feedback, and work closely with the Tissue Viability Team, to make sure the tentative hypotheses remain relevant to practice.

5.2.2 Stage 2

In our first protocol (v1.0) we proposed that we would develop the method as we carried out the research (see Section 8.1 Developing the method). While carrying out Stage 1, we found there were areas of potential bias which need addressing, and this has meant slight changes to the design of the study, collecting the data in a slightly different manner, and analysing the data differently.

We have identified a need for:

a) Closer professional involvement to help guide data collection

b) An expert panel to provide feedback on evidence.

c) A 'good usual care' account to balance the data

Methodology

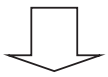
After initial case note review, interview data collection and documentary analysis, the researcher will feed back findings at length to an on-site Principal Investigator (PI), who will conduct a parallel case note review and look over the initial patient interview. This will help

to interpret the data with expert advice. The researcher will then collect further data, which will be discussed again with the PI. This process will help the researcher construct a fully 'coherent account' of how the pressure ulcer developed, which will remain grounded in practice and informed by professional judgement.

Stages of expert involvement in the research process:

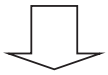
Stage A (which is iterative, and stages can be repeated)

Data collection Patient interview/patient notes (researcher)

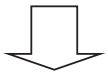


Parallel case note review by researcher and site principal investigator (PI)

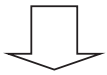
Researcher discusses data collection with Site Principal Investigator



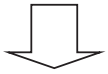
Researcher gathers more data, anonymises and builds coherent account in collaboration with PI



Coherent account overseen by subgroup (n=3) consisting of two TVNs (not onsite PI: one hospital TVN; one community TVN) and one non-clinical academic



Sub group comments incorporated into account



Coherent account overseen by Chief Investigators of project team (n=2). Comments incorporated into account.

The account will then be overseen by the Chief Investigators, who will help to create a final version of a coherent account of the second, and further cases, and limit any researcher bias as far as possible.

At this point the data will be anonymised according to Leeds University Clinical Trials Research Unit guidelines on data confidentiality. The data will then be encrypted for further security, and to allow access by the rest of the research team. The anonymised and encrypted

coherent account of the first case will then be presented to a further panel of experts (which consists of two tissue viability nurse specialists and a non-clinical academic), who do not have direct clinical involvement with the patient. They will check the account for validity using evidence from the documentation, and their comments will be incorporated. This will help avoid individual researcher bias and provide a transparent trail of evidence (Yin, 1994).

'Good usual care' account

For all cases after Patient 1, we have chosen to combat some of the sources of bias, by constructing an account of 'good usual care'. This normative account will provide a benchmark against which the care of the patients in the study can be judged. The 'good usual care' account will also provide a way of minimising effects of bias i.e.:

i) Clinicians' beliefs
ii) PURPOSE team beliefs
iii) Weighting of different perspectives in patient accounts
iv) Hindsight bias

The account will:

1. Draw on national guidance such as the NICE guidelines key recommendations (RCN, 2001; 2005).
2. Include a summary of local site protocol recommendations as set out by the site Tissue Viability Nurse.
3. Include information not available from points 1 and 2, which incorporates information from Tissue Viability Nurse specialists as expert witnesses, and further information from interviews with various stakeholders.
4. Be mapped against the actual chronological events within a case to look for points of commonality and for events which do not meet the 'good usual care' criteria.

Please see below for a summarised example account strategy, as it would be mapped against actual chronological events. The account will be more detailed, and consists of two tables, one which incorporates key events by data source, and these are then cross referenced to our external judgement criteria table:

Source of data (below)	Time 1	Time 2	Time 3

	30 March 2009 (patient notes)	2 April 7pm	2 April 9pm
Patient/nursing notes	Significant event 1 Patient admitted for surgery with SPU.	Event 2 Patient prepared for surgery.	Event 3 Patient returned from surgery.
Patient's version of events	Waiting since January for surgery.		
Consultant's version of events			Consultant instructed patient to be turned L and R side every 3 hours.
Ward Manager's version of events			Patient was being difficult about turns.
Significant others' version of events, e.g. TVN, HCA, Informal carer			Nurses note turns
Organisational information/details	Patient admitted to a surgical ward.		Ward really busy. Understaffed (staff off duty)

The above data sources will be cross tabbed against external criteria as follows:

	Event 1	Event 2	Event 3
	Patient not risk assessed (no record in notes)	Patient admitted onto ward and not turned	
Local protocol guidelines	Patient should be Risk assessed using Waterlow scale, Care plan written up…	Turning regime should be followed as per patient care plan.	Ward requires one qualified staff per patient at all times
NICE guidelines	Patients should receive		All patients should be

	initial and ongoing PU assessment. Ulcer assessment should include: cause of ulcer…etc.		monitored post op etc.
Specific clinical/co morbid risks for patient	Older age, diabetes		There is a risk post op of low blood pressure.
Expert witness account of usual care	Normally patients will receive a care plan assessment, and will always undergo a Risk assessment.		
Weighted evidence. Does the event meet expected criteria?			

The first case, from Stage 1 will be compared with 4 or 5 further cases. These will be selected to present with the widest possible range of personal and service characteristics (see Inclusion Criteria). We will use evidence from this stage to refine the initial coherence account. It may be that there are no plausible explanations at this point, in which case another patient will be chosen with an unexpected pressure ulcer or few known clinical risk factors once again. Again, the aim will be refining the coherence account of the patient's experience, using the same methods of gathering evidence as in Stage 1.

Using a 'building block' approach to sampling (Blaikie, 2000; Pawson, 2006) more cases will be selected which are best able to help develop explanations. The coherence account will become more refined as up to 6 more cases are compared (a maximum of 12 cases). Hypotheses around plausible explanations why a patient should develop a severe pressure ulcer, will be confirmed or refuted as more evidence is gathered (see Ragin, 2000). This may be apparent by just a few patients, or may need all 12 patients before we are able to start to

make generalisations. This might also involve retracing steps and looking for further evidence to elaborate the existing coherence account, as further evidence is uncovered.

In this stage, and through all stages of the research, we will work closely with the Tissue Viability Team (TVT) and provide regular feedback to staff verbally, and with summary reports, so that the explanations we offer remain constantly relevant to practice. For example; if a patient's movement through services appears, once again, to have a possible impact on severe pressure ulcer development, we would look to confirm this hypothesis with further cases. Stage 2 will conclude with a refined version of the coherence account, which will be used to produce an explanatory model to explain why patients develop Category 3 and 4 pressure ulcers.

The model(s) will be implemented into a critical incident/adult neglect review protocol as part of future joint work with Study 3 (NIHR Pressure Ulcer Programme). This will also inform a severe pressure ulcer risk assessment framework. See flowchart 5.3 below.

Sections 6, 7, 8 METHOD (INCLUDING ANALYSIS)

6 ELIGIBILITY

6.1 Inclusion Criteria

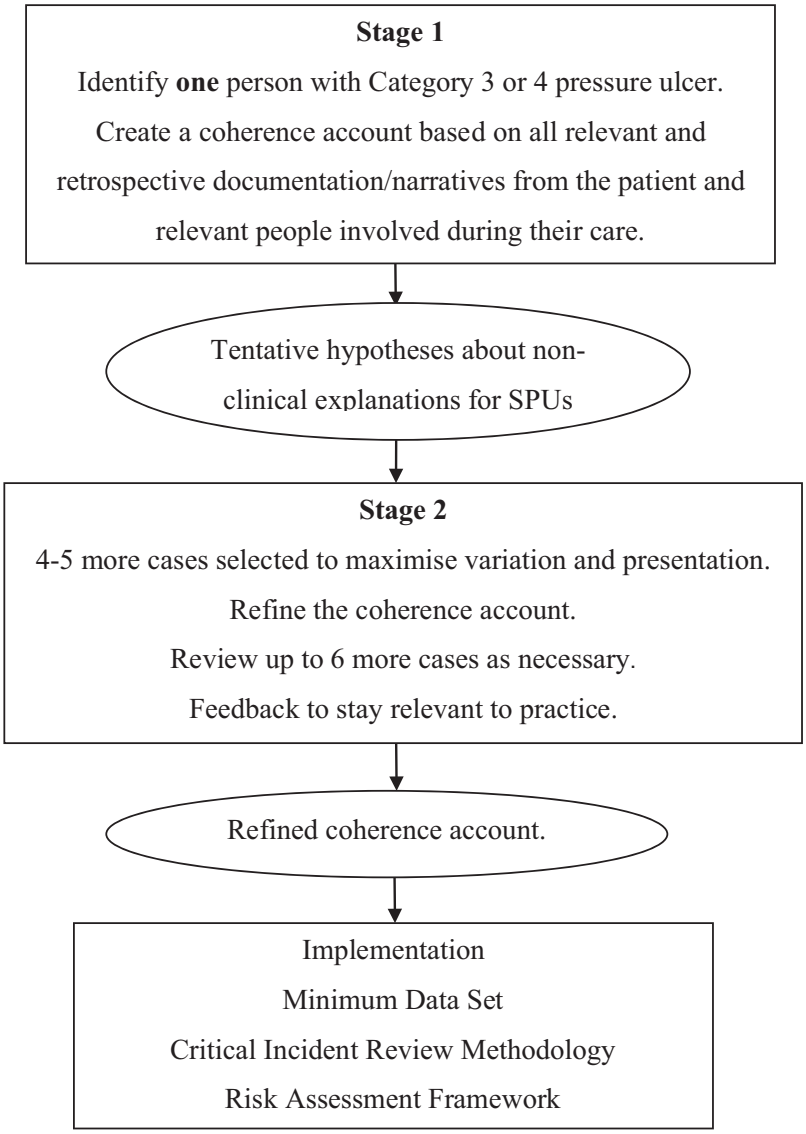
(Stage 1) will include one participant who has few clinical risk factors, e.g. an elective orthopaedic patient (Nixon, 2007) who presents with a Category 3 or 4 Pressure Ulcer.

Table 1. EPUAP Pressure Ulcer Classification System[4]

Category	Description
Category 0	Normal
Category 1 Non-blanchable erythema of intact skin	Intact skin with non-blanchable erythema of a localised area usually over a bony prominence. Discolouration of the skin, warmth, oedema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.
Category 2 Partial thickness skin loss or blister	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum or sero-sanginous-filled blister.
Category 3	Full thickness tissue loss. Subcutaneous fat may be visible

Full thickness skin loss	but bone, tendon or muscle are *not* exposed. Some slough may be present. *May* include undermining and tunnelling.
Category 4 Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. *Often* includes undermining or tunnelling.
Category U	Unstageable

5.3 Flowchart of research design:



For Stage 2, four or five patients from participating acute and community trusts will be chosen if they have had or have currently a Category 3 or 4 pressure ulcer (EPUAP 2008). These may include hospital in-patients, hospital out-patients, intermediate care or community patients under the care of community nursing services. This stage will aim to maximise variation and presentation of severe (Category 3 and 4) pressure ulcers. The sample will also be monitored for anatomical site of the pressure ulcer (e.g. heel, sacrum, buttocks) to allow for variation amongst patients. Further participants will be chosen following the procedures set out in the research design.

6.2 Exclusion Criteria

Patients who it would be ethically inappropriate to approach, for example, those where death is imminent, will not be approached.

Additionally, patients who are unable to tell their story (narrative) of their experience will be excluded, as this forms part of the main design of the study.

7 RECRUITMENT AND CONSENT PROCEDURE

7.1 Patients (ward based)

Members of the tissue viability team (TVT) which includes the local principal investigator and other members of their local team (i.e. tissue viability nurse specialists and clinical research nurses) at participating trusts will screen potentially eligible patients through critical incident reporting systems, healthcare records and referrals. The patients will be approached by a member of the TVT, informed about the study, and provided with a project information leaflet which includes details about the rationale, design, and personal implications of the study and an 'agree to be contacted by the researcher' form. Members of the TVTs at participating trusts will provide an anonymous record of patients identified as potentially eligible, approached to participate, refusals, and those agreeing to be contacted.

Following information provision, patients will have as much time as they need to discuss the study with their family, advocate, carers, and healthcare provider. They will be asked to complete the 'agree to researcher contact' form, which will be posted back to the Centre for Health and Social Care. The TVT and the researcher will be available to answer any questions that patients might have about the study. After receiving the signed 'agreement to

be contacted' form from the patient, the researcher will contact the patient, carer, healthcare professional etc. to arrange a convenient time for possible interview and written consent. The researcher will provide information about the study and interview process and will answer any questions before gaining verbal consent and arranging an interview at a mutually convenient time. For in-patients who cannot be contacted by telephone and who are expected to be in the hospital during the interview, the TVT member will liaise with the researcher and patient to arrange a mutually convenient time for the researcher to see the patient on the ward to discuss the study further, and seek written consent or conduct an interview.

The researcher will interview patients in their own home, in the out-patient clinic, or in-patient ward, as determined by the patient's circumstances and preferences at the time of the interview. Before the interview, each participant will be given a further verbal explanation of the study by the researcher, informed that the interview will be recorded but that all identifiable information will remain anonymous, reminded that they can withdraw from the study at any time without it affecting their care, and then invited formally to participate. They will be given an opportunity to ask any questions and then if they agree to take part, the participant will be asked to sign the consent form. A copy of the consent form will be given to the patient to keep, one copy will be filed in their healthcare records, and the original will be kept by the researcher and filed securely in the Study Master File at the Centre for Health and Social Care.

The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time, again, without giving reasons and without prejudicing any further treatment.

7.2 Patients based in the community

A similar approach to the above ward-based procedure will be followed; however this will involve a third stage:

Members of the tissue viability team (TVT) will screen potentially eligible patients through critical incident reporting systems, healthcare records and referrals. The patients will be approached by a member of the TVT, informed about the study, and provided with a project information leaflet, which includes details about the rationale, design, and personal implications of the study, and an 'agree to be contacted by the researcher' form. Members of

the TVTs at participating trusts will provide a record of those identified as potentially eligible, approached to participate, refusals, and those agreeing to be contacted.

Following information provision, patients will have as much time as they need to discuss the study with their family, advocate, carers, and healthcare provider. They will be asked to complete the 'agree to researcher contact' form, which will be posted back to the Centre for Health and Social Care). The TVT and the researcher will be available to answer any questions that patients might have about the study.

After receiving the signed 'agreement to be contacted' form from the patient, the researcher will accompany a TVT member and personally introduce the researcher to the patient in their home. The researcher will provide information about the study and interview process and will answer any questions before gaining possible verbal consent, and then arranging an interview at a mutually convenient time, where written consent will be sought. This will allow for the patient to feel more comfortable with the researcher at a second meeting, as part of the study is to get a narrative account from the patient's perspective. In this way, the patient will feel also less vulnerable being alone with the researcher.

7.3 Stakeholders involved in the patient's care 'pathway', for example their informal carer, advocate, nursing staff, paid carer, other healthcare provider.

After the patient has been approached, given his or her consent, and interviewed, carers and healthcare professionals involved throughout their care pathway will be sought out through the patient interviews and examination of the patient's healthcare records, and any other documentation concerned with their care, and using an approach similar to that of patient recruitment, except that carers and staff will be approached directly (face to face or by phone) and asked if they would be interested in participating. Information will be provided about the study and a 'cooling off' time will be allowed before their consent is sought to take part. The guidelines will follow those of the patient consent procedure apart from this initial difference in approaching participants. A snowballing technique will be used to enlarge the sample until data saturation is reached.

8 PROCEDURES/DATA COLLECTION/ANALYSIS

In principal patient interviews will be undertaken prior to documentary analysis to ensure the researcher does not absorb any preconceived ideas from patient documentation about the causes of severe pressure ulcers. A step by step approach will be used:

8.1 Stage 1 (Case 1)

Developing the method (see Perrow, 1984; Vaughan, 1996)

1. An in-depth interview with the patient (and carers if appropriate) to gain his or her personal story of how their pressure ulcer developed. Interviews will be recorded
2. The researcher will then access patient case notes/healthcare records and patient held records. Nurses, GPs and other healthcare professionals who have a responsibility regarding their patient's records will be kept fully informed of the study, and a mutually convenient time will be arranged to access the records. We will examine the notes using a range of practical tools:
    a. Timelines to record the main sequence of event s (e.g. movements between wards)
    b. Records of where key players were and other relevant people,
    c. Chronological accounts of key events, sometimes referred to as clinical incident sheets

We may use other methods, which will be identified while collecting data, to help further with our systematic searching. All the documentary analysis will be done on site, e.g. NHS ward, patient's home, care home, which will avoid issues with confidentiality.

We will use the data to create a coherence account, as described in Section 5. The analysis will run in parallel with data collection, and begin after the first interview. The academic process involves developing a clear account using and refining our evidence, and 'this interaction of ideas and evidence leads to theories based on what we have analysed' (Ragin, 1994). Software (NVivo 8; QSR) will be used as an aid to organise and categorise the data.

Other people will be sought out who are relevant to the patient's story of how their pressure ulcer started. These participants will also be chosen according to what evidence is found from relevant documentation. We will conduct in-depth interviews with the chosen participants (see Topic guide). The people chosen in Step 3 are likely to include informal and professional carers, nurses and other professionals involved in the care of the patient, but they could be

anyone who has been identified as having an influence in the development of the pressure ulcer, by the patient or by documentary evidence.

8.2 Stage 2 (cases 2, 3, 4, 5, 6 up to 12)

We will use the same methods of data collection as Stage 1 for the next four or five more cases. In-depth interviews and documentary evidence will be used to help refine our coherence account. We will then continue to collect data for more cases (up to 12) to refine the coherence account.

If we have to review the first case, or previous cases, to look for more evidence which supports newly uncovered insights (see study design) and refine our coherence account we will do this looking for newly relevant data. As the data set builds, the process of analysis will be refined and more causal explanations will be generated until saturation point is reached. Verbal feedback and summary reports will be sent to Tissue Viability team.

The findings and conclusions drawn will provide a structured, theory informed basis from which to develop an adult incident critical incident methodology and risk assessment protocol. The findings will be used in practice at pilot sites, if the models are found to be explanatory.

8.3 Flow chart of data collection /consent seeking process:

Possible patients identified using critical incident reporting and caseload review by TVTs, and according to minimum clinical risk factors

TVTs contacts researcher and researcher identifies first case

TVT approaches patient to seek ‘researcher contact’

Researcher contacts the patient to seek verbal consent and arrange interview

Researcher conducts in-depth interview with patient

Researcher searches documents and healthcare records related to patient pathway.

Researcher seeks consent for interview from other relevant stakeholders in patient pathway (identified in patient documents/interviews).

Tentative hypotheses developed arising from case 1

4 -5 further cases identified using hypotheses/potential explanations from Case 1

Process repeats until no more potential explanations can be found.

9 DATA ANALYSIS

The analysis of the interview and documentary data will be conducted in parallel with the data collection (see Section 6). This will include ongoing analysis following the procedures set out in the study design (Section 5), i.e. sifting through and refining the data over and over again until causal explanations are produced. NVivo 8 (QSR) software will be used to organise the data.

12 ETHICAL CONSIDERATIONS

This project will recruit patients with Category 3 and 4 PUs and will therefore include elderly and highly dependent patients considered as vulnerable. Ethical issues relate to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. The study also raises ethical issues in relation to recruiting patients who may have fluctuating lack of capacity; however this will be assessed at the time of consent seeking. The ethical issues surrounding these potentially vulnerable patients have

been addressed through the study design and include a thought out consent process, which also follows current Mental Capacity Act guidelines.

If any patient or other person involved in his or her care pathway were to disclose an instance of abuse or neglect, this subject will be discussed with the patient, and the researcher will inform the closest professional or carer depending on the circumstances. This will be explained to the participant before the interviews take place.

The study will be submitted to and approved by a flagged Research Ethics Committee (REC) prior to identifying eligible patients. The Centre for Health and Social Care will provide the REC with a copy of the final protocol, patient, staff and informal caregiver information leaflets, consent forms, and all other relevant study documentation.

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Appendix 11 Severe pressure ulcer study participant information leaflet and agree to research contact form

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Why do patients develop severe pressure ulcers? Patient interviews (community based; version 3 (04/02/2010)

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse or carer if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

The development of a severe pressure ulcer (PU), also called a bed sore or pressure sore, has serious consequences for everyone involved. For patients, they cause much suffering and pain. For staff involved in the care of someone with a severe pressure ulcer, they are now seen as what is called a 'serious clinical incident', and require investigation into the causes. For carers they are a major worry, and an obstacle to caring.

This study is about trying to find out the reasons why people develop severe pressure ulcers which may not always be clinical ones. One of the purposes of this study is to see whether the causes may be down to healthcare system weaknesses, rather than to individual weaknesses or blame. The study involves interviewing patients like yourself, and all the people involved in your care throughout the development of your severe pressure ulcer, to see if there are any general underlying patterns which lead to developing a severe pressure ulcer. The study also aims to uncover any other reasons for developing a severe pressure ulcer, which may have not yet been noticed. The final aim of the study is to help produce a risk assessment tool, which will try to help prevent severe pressure ulcers from developing.

Why have I been invited?

You have been chosen to take part because we are interested in talking to people who have experience of having severe pressure ulcers. Any person who has, or has had in the past, a severe pressure ulcer, from a sample of either hospitals or within the community, will be asked to participate.

Do I have to take part?

You are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part we will then ask you to sign a consent form to show that you have agreed to take part. You will be given a copy of this information sheet and the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What will happen to me if I take part?

If you agree to take part, you will be introduced to the researcher, who will be accompanied by the tissue viability nurse. This will give you an opportunity to ask questions about the study. If you then still wish to take part, the researcher will arrange an interview with you. It is expected that the interview will take about an hour. We will make sure the interview takes place in as private a place as possible, either in your own home or on the ward where you are admitted, at a time convenient for you. The interview will be informal, in a conversation style, rather than a list of questions.

The researcher will also seek permission to access and analyse your case notes, to look into what possibly led to you developing a severe pressure ulcer. Your nurses and carers/relatives will be approached to participate in the research and provide information relating to your care. No further involvement from you is required.

The discussion that you have with the interviewer, with your permission, will be tape recorded and transcribed to help us analyse it. The tape recording will be used only by

researchers involved in the project and it will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and you will need to reflect on your personal experience of having a severe pressure ulcer and what your experience of care has been. There is a possibility that you may find this distressing. The interview can be stopped at any point if you feel you do not want to continue. If necessary, a referral can be made to your nurse or other healthcare professionals if you are distressed at all by the interview.

What are the possible benefits of taking part?

We hope that being given the opportunity to take part in this study would give you some satisfaction that you are contributing to increasing knowledge about the reasons and risks behind why people develop severe pressure ulcers. We hope that the information we get from the interviews will help to inform healthcare services about patterns in a person's care pathway which may be more likely to lead to the development of a severe pressure ulcer. We also hope to help produce a risk assessment to help prevent severe pressure ulcers from occurring.

Will my taking part in this study be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first. Details are included in Part 2.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You are free to change your mind at any point up to, during or following the interview. You will not be able to be identified in the study results but if you wish to withdraw any data already collected prior to publication of the results then arrangements can be made for the interview tape to be destroyed and your discussion excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Caldicott principles and the Data Protection Act 1998.

Lisa Pinkney and her supervision team have a duty of confidentiality to you as a research participant and will do their very best to meet this duty. Any information that is collected about you will have your name and address removed so that you cannot be recognised. All information will be kept in locked cupboards and will only be accessible by members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be used to inform healthcare provision, and to help produce a risk assessment tool, based on the information gathered from participants. Information from this study will be included in a final report and published in a scientific journal.

Who is organising and sponsoring the research?

This study is funded by the National Institute of Health Research, which is part of a larger pressure ulcer research programme aimed to reduce the impact of PUs on patients, and to

produce a risk assessment framework to help prevent pressure sores. This study is also being undertaken as part of a PhD qualification supervised by the University of Leeds.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the *Leeds West* Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please tell your district nurse or tissue viability nurse who provided you with this information leaflet. They will complete the Agree to Researcher Contact Form at the end of this leaflet and send it back to the researcher, Lisa Pinkney, who will contact you upon receiving the form, to discuss this study further (with your tissue viability nurse present) and then arrange a time for the interview.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Lisa Pinkney on 0113 343 0828 or the study supervisor, Professor Justin Keen on 0113 3436941 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

[Delete this line then print on Trust headed paper- given with study information]

PATIENT AGREEMENT TO RESEARCHER CONTACT

Name of researcher:

Lisa Pinkney
Centre for Health and Social Care
University of Leeds
Leeds Institute of Health Sciences
101 Clarendon Road
Leeds
LS2 9LJ
0113 343 0828

Name of consultant/nurse: _____

Contact number: _____

Why do patients get severe pressure ulcers? Patient interviews

Please initial the boxes:

- I have read the information sheet (version 3) and kept a copy. ☐

- I am happy to be contacted by the above named researcher to discuss the study further (with a tissue viability nurse present) ☐

Please complete your contact details in the space provided

Patient name _____

Address _____

_____

_____Postcode_____

Telephone Number _____

Preferred contact time _____

Thank you for completing this form. Please return to Lisa Pinkney at Centre for Health and Social Care, Room 2.02, LIHS, University of Leeds, 101 Clarendon Road, Leeds, LS2 9LJ or phone 0113 343 0828.

Appendix 12 Severe pressure ulcer study consent form

[Delete this line then print on headed paper]

Why do patients develop pressure ulcers? Consent form version 3 (4/2/2010)

Name of researcher: Lisa Pinkney
Address: Centre for Health and Social Care, University of Leeds, Institute of Health Sciences, 101 Clarendon Road, Leeds, LS2 9LJ **Telephone:** 0113 3430828

	Please initial box after each question
1. I confirm that I have read and understand the information sheet for the above study *Version 3 dated* 4/2/2010and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected.	☐
3. I understand that the above named researcher may ask my nurse, caregiver or other people relevant to my care, additional information about my pressure ulcer history and relevant treatment. I give permission for the researcher to access my healthcare records e.g. hospital nursing, and GP records to obtain further information for the above study and any further research that may be conducted in relation to it, provided that strict confidentiality is maintained.	☐
4. I agree that my interview will be tape recorded and typed out, maintaining anonymity.	☐
5. I agree to allow any information arising from this study to be used for healthcare and/or medical research purposes. I understand my identity will remain anonymous.	☐
6. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication.	☐
7. I understand that a copy of this Consent Form will be sent to the Centre for Health and Social Care and my GP.	☐
8. I agree to take part in the above study.	☐

Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Name of Person taking consent	Date	Signature

(When completed, 1 for patient, 1 for patient file; 1 for CHSC)

Appendix 13 Severe pressure ulcer study topic guide

'Why do patients develop severe pressure ulcers?' study

Researchers: Lisa Pinkney, Professor Justin Keen, Dr Jane Nixon

Address: Centre for Health and Social Care, University of Leeds, Leeds, LS2 9LJ

Tel.: 0113 343 0828

Interview topic guide: patients

(Verbal introduction . . .) Have you any questions about this study? Are you happy to start the interview?

This interview will be unstructured and informal and guided by you, not by a set of questions. However, as an opening question . . .

Introductory question: Why do you think you developed a severe pressure ulcer?

Some topics that will be covered but which are only tentative topics and which will be developed as the research progresses:

- background/history of events
- severe pressure ulcer description
- timeline of events – micro, mezzo and macro levels
- interpersonal level
- people involved
- support systems – people, services
- clinical risks
- unexpected events
- communication
- service involvement.

Appendix 14 Search strategies and data sources

Search strategy for the systematic review of patient risk factors for pressure ulcer development

Four electronic databases, AMED, MEDLINE, EMBASE and CINAHL, were searched from inception until March 2010 through the Ovid web gateway from their inception using the search template detailed below. The search plan included pressure ulcer search terms and Ovid maximum sensitivity filters for prognosis and aetiology or harm.

1. decubitus.sh.
2. skin ulcer.sh,tw.
3. exp decubitus ulcer/
4. decubitus ulcer$.tw.
5. PU$.tw.
6. pressure damage$.tw.
7. pressure sore$.tw.
8. bed sore$.tw.
9. or/1-8
10. exp cohort-studies/
11. exp risk/
12. (odds and ratio$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
13. (relative and risk$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
14. (case and control$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. or/10-14
16. incidence.tw.
17. exp mortality/
18. Follow-Up Studies/
19. prognos$.tw.
20. predict$.tw.
21. course.tw.
22. Survival Analysis/
23. or/16-22
24. 9 and 15
25. 9 and 23
26. 24 or 25
27. case report.sh.
28. historical article.pt.
29. review of reported cases.pt.
30. review, multicase.pt.
31. letter.pt.
32. comment.pt.
33. editorial.pt.
34. or/27-33
35. 26 not 34
36. limit 35 to humans

The first 200 retrieved abstracts were screened and key words from non-relevant papers were identified and used to further refine the search (i.e. increase specificity):

37. leg ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
38. varicose ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
39. pilonidal.tw.
40. surgical flaps.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
41. skin transplantation$.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
42. burn$.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
43. gunshot.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
44. corneal ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
45. exp dentistry/
46. peptic ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
47. duodenal ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
48. stomach ulcer.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
49. fistula$.mp. [mp=ab, hw, ti, it, sh, tn, ot, dm, mf, nm]
50. bite.tw.
51. or/37-50
52. 36 not 51

Hand searching

The following specialist journals and conference proceedings were hand searched.

Journals

- *Journal of Tissue Viability*, 1990 to present.
- *Journal of Wound Care*, 1991 to present.
- European Pressure Ulcer Advisory Panel reviews, volume 1, issue 2, 1999 to volume 7, issue 2, 2006.

Conference proceedings

- Proceedings of the 1st European Conference on Advances in Wound Management, September 1991, Cardiff, UK.
- Proceedings of the 2nd European Conference on Advances in Wound Management, October 1992, Harrogate, UK.
- Proceedings of the 3rd European Conference on Advances in Wound Management, October 1993, Harrogate, UK.
- Proceedings of the 4th European Conference on Advances in Wound Management, September 1994, Copenhagen, Denmark.
- Proceedings of the 5th European Conference on Advances in Wound Management, November 1995, Harrogate, UK.
- Proceedings of the 6th European Conference on Advances in Wound Management, October 1996, Amsterdam, the Netherlands.
- Proceedings of the 7th European Conference on Advances in Wound Management, November 1997, Harrogate, UK.
- Proceedings of the 8th European Conference on Advances in Wound Management, April 1998, Madrid, Spain.
- Proceedings of the 9th European Conference on Advances in Wound Management, November 1999, Harrogate, UK.
- Proceedings of the 10th European Conference on Advances in Wound Management, May 2000, Stockholm, Sweden.

- Proceedings of the 11th Conference of the European Wound Management Association, May 2001, Dublin, Ireland.
- Proceedings of the 12th Conference of the European Wound Management Association, May 2002, Granada, Spain.
- Proceedings of the 13th Conference of the European Wound Management Association, May 2003, Pisa, Italy.
- Proceedings of the 15th Conference of the European Wound Management Association, September 2005, Stuttgart, Germany.
- Proceedings of the 16th Conference of the European Wound Management Association, May 2006, Prague, Czech Republic.
- Proceedings of the European Wound Management Association and *Journal of Wound Care* Conference, April 1997, Milan, Italy.
- Proceedings of the European Wound Management Association and *Journal of Wound Care* Autumn Conference, November 1998, Harrogate, UK.
- 2nd World Union of Wound Healing Societies Meeting, July 2004, Paris, France.
- *Journal of Wound Healing* 2nd Conference, September 2005, Stuttgart, Germany.
- Wounds UK Conference, November 2004, Harrogate, UK.
- 1st European Pressure Ulcer Advisory Panel Open Meeting, September 1997, Oxford, UK.
- 2nd European Pressure Ulcer Advisory Panel Open Meeting, September 1998, Oxford, UK.
- 3rd European Pressure Ulcer Advisory Panel Open Meeting, September 1999, Amsterdam, the Netherlands.
- 4th European Pressure Ulcer Advisory Panel Open Meeting, September 2000, Pisa, Italy.
- 5th European Pressure Ulcer Advisory Panel Open Meeting, September 2001, Le Mans, France.
- 6th European Pressure Ulcer Advisory Panel Open Meeting, September 2002, Budapest, Hungary.
- 7th European Pressure Ulcer Advisory Panel Open Meeting, September 2003, Tampere, Finland.
- 8th European Pressure Ulcer Advisory Panel Open Meeting, May 2005, Aberdeen, Scotland.
- European Tissue Repair Society, Focus Meeting, November 2000, St Anne's College, Oxford, UK.
- European Tissue Repair Society, Annual Conference, September 2001, Cardiff, UK.
- European Tissue Repair Society, Focus Meeting, September 2002, Nice, France.
- 13th Annual European Tissue Repair Society Meeting, September 2003, Amsterdam, the Netherlands.
- European Tissue Repair Society, Focus Meeting, March 2005, Southampton, UK.

Appendix 15 Example evidence table for subdomain oedema

Author and year	Study quality	Study limitation notes	Study design	PU events/sample	Specific variable	OR	CI	Study population
[a]Compton *et al.* 2008[144]	Low-quality study	Record review. Large number of events but used 32 variables in the model. No CIs reported	Record Review	121/698	Skin condition oedematous skin	2.245	NR	Acute care hospital, ICU, non-surgical
Nijs *et al.* 2009[159]	Moderate-quality study	Full details of modelling not provided. Adequate number of events is assumed as large number of events	Cohort	134/463	Pitting oedema	NR	NR	Acute care hospital, ICU, surgical
Bergquist and Frantz 1999[134]	Low-quality study	Record review and insufficient number of events. Inadequate measurement of risk factors	Record Review	55/1567	Oedema	NR	NR	Community/ home care, elderly/ geriatric, non-surgical
Donnelly 2006[146]	Low-quality study	Insufficient number of events and no CIs reported	RCT	39/239	Oedema	HR 1.023	NR	Acute care hospital, elderly/ geriatric, hip fracture

HR, hazard ratio; ICU, intensive care unit, NR, not reported; RCT, randomised controlled trial.
a Study in which the specific variable emerged as a risk factor in multivariable analyses; in all other studies the specific variable did not emerge as a risk factor in multivariable analyses.

Appendix 16 Consensus study reduced format protocol

NB: This study protocol (version 2, dated 14 September 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request

4.1 Study aims

This study aims to:

1. Agree a Pressure Ulcer Minimum Data Set (PU-MDS)
2. Develop an evidence based Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice.

5 STUDY DESIGN

5.1. Overview of Study Design

This study will utilise structured consensus methods and will be underpinned by a PU risk factor systematic review (Nixon et al) and emerging evidence from the PURPOSE studies.

5.2 Overview of Consensus Process

ASPECT		Month	Event	Activity
PU-MDS		Sept 2010	Working Group	Pre nominal group work-up: • Identify specific issues to be examined • Methodologist review and synthesis research evidence • Develop and pilot questionnaire #1A
PU-MDS		Oct/ Nov 2010	PU-MDS Nominal Group (Meeting 1)	Pre-meeting: NG members complete questionnaire #1A
PU-MDS		Nov/ Dec 2010		At meeting • Present results of review of evidence synthesis • Presentation of results of questionnaire #1A

				• Exploration of areas of disagreement
PU-MDS		Dec 2010		After meeting • Revise questionnaire (#1A →#1B) and NG members complete questionnaire #1B
PU-MDS		Jan/ Feb 2011	Consultation	Wider international completions of questionnaire #1B by a sample of approximately 200 researchers and clinicians recruited via PU/ Wound care Organisations.
	PURAF	March 2011	Working Group	Pre nominal group work-up: • Identify specific issues to be examined • Methodologist review and synthesis research evidence • Develop and pilot questionnaire #2A
PU-MDS		March 2011	PU-MDS Nominal Group (Meeting 2)	Pre-meeting: collate results of questionnaire #1B
PU-MDS		May 2011 (same day as 1st PURAF meeting)		At meeting • Presentation of results of questionnaire #1B • Exploration of areas of disagreement • Agreement of final PU-MDS
	PURAF	April 2011	PURAF Nominal Group (Meeting 1)	Pre-meeting: NG members complete questionnaire #2A
	PURAF	May 2011 (same day as 2nd PU-MDS meeting)		At meeting • Present results of review of evidence synthesis • Presentation of results of questionnaire #2A • Exploration of areas of disagreement
	PURAF	May/ June 2011		After meeting • Revise questionnaire (#2A →#2B) and NG members complete #2B
	PURAF	June/ July 2011	Consultation	Wider international completions of questionnaire #2B by a sample of approximately 200 researchers and clinicians recruited via PU/ Wound care

				Organisations.
	PURAF	August –Nov 2011	PURAF Nominal Group (Meeting 2)	Pre meeting: Collation of results of questionnaire #2B
	PURAF	Nov/ Dec 2011		At meeting • Presentation of results of questionnaire • Exploration of areas of disagreement • Agreement of final PURAF

5.3 PU-MDS Development

Using the evidence from the PU risk factor systematic review (Nixon et al) and emerging evidence from the other PURPOSE programme studies a questionnaire will be developed by the working group to elicit the views of the PU-MDS nominal group members in relation to data items for inclusion in the PU-MDS. The nominal group will comprise 12-14 key stakeholders/ experts in the area of PU risk / development / research / practice and they will be asked to complete the questionnaire (#1A) after reviewing a summary of the PU risk factor systematic review.

The PU- MDS nominal group will then have a series of two face to face meetings which will be carefully led by experienced facilitators and will be observed, audio taped and transcribed to allow thematic analysis of issues affecting final ratings. The terms of reference will be fully articulated at each meeting.

The first meeting will allow the initial questionnaire (#1A) results to be presented to the group and areas of disagreement discussed and explored. The questionnaire will be revised following the meeting (#1B) and the nominal group members will be invited to re-complete the questionnaire privately which will determine the levels of consensus within the group in relation to the criteria for inclusion in the PU-MDS. The purpose of the questionnaire is to find out what items experts think are required in a minimum data set (MDS), using the systematic review data as the initial list of possible items.

Prior to the second nominal group meeting the PU-MDS questionnaire #1B will be administered, via a web-based survey tool to a wider representative group to test the consensus views of the nominal group in relation to the factors for inclusion in a PU-MDS.

We aim to recruit 200 researchers and clinicians to be involved in this part of the study. Participants will have access to the PU a summary of the systematic review as well as the nominal groups' views.

At the second nominal group meeting the results of questionnaire #1B, the wider PU-MDS consultation will be presented and discussed and the final PU-MDS will be agreed.

5.4 PURAF Development

Using evidence from the PU risk factor systematic review (Nixon et al), emerging evidence from the other PURPOSE programme studies and the results from the PU-MDS wider consultation the working group will develop a PURAF questionnaire to elicit the views of the PURAF nominal group members in relation to the value of key risk factors in both PU risk screening and detailed PU risk assessment. A similar staged process detailed as above will be adopted. The nominal group will complete questionnaire #2A in advance of the first PURAF nominal group meeting.

The first PURAF meeting will allow the initial questionnaire (#2A) results to be presented to the group and areas of disagreement discussed and explored. The questionnaire will be revised following the meeting (to form questionnaire #2B) and nominal group members will be invited to re-complete the questionnaire privately which will determine the levels of consensus within the group in relation to the components and format for PURAF.

Prior to the second nominal group meeting the PURAF questionnaire #2B will be administered via a web-based survey tool to a wider group to test the consensus views of the nominal group in relation to the components and format for the PURAF. We aim to recruit 200 researchers and clinicians to be involved in this part of the study. Participants will have access to the PU risk factor systematic review summary report as well the nominal groups' views.

At the second nominal group meeting the results of the wider PU-MDS consultation will be presented and discussed and the final PURAF will be agreed.

6 STUDY PARTICIPANTS

6.1 Nominal Group Membership

Nominal group members will be purposively sampled ensuring representation of researchers and clinicians with expertise in the following areas:

- Vascular/ perfusion/ diabetes
- Nutrition
- Biomedicine
- Dermatology
- Minimum Data Set
- Psychology
- Pressure ulcer research
- Tissue Viability
- Statistics
- Organisational Development
- Software engineering

The role of the PU-MDS nominal group is to agree a PU-MDS. The role of the PURAF nominal group is to develop an evidence based PURAF.

6.2 Working Group Membership

The working group will comprise of PURPOSE PU academic and clinical leaders including Jane Nixon (Chief Investigator), Susanne Coleman (Project Lead/ researcher), Andrea Nelson (multi-centre health services research) Carol Dealey, Lyn Wilson, Elizabeth McGinnis, and Nikki Stubbs (clinical expertise) and Michelle Collinson and Julia Brown (statistical expertise). The role of this group is to support the nominal group to identify specific issues to be examined, to develop questionnaires and to synthesis research evidence for consideration.

6.3 Wider Consultation Participants

The wider consultation participants will include individuals with similar expertise of the nominal group members as well as clinical users. They will not be required to attend face to face meetings. This group will allow the consensus views of the nominal groups to be tested by a larger group

7 RECRUITMENT AND CONSENT PROCEDURES

7.1 Nominal Group Participant

Potential PU-MDS and PURAF nominal group participants will be identified via the literature pertaining to pressure ulcers and/or membership of pressure ulcer related professional organisations, including the Tissue Viability Society, European Pressure Ulcer Advisory Panel, the National Pressure Ulcer Advisory Panel, Japanese Society of Pressure Ulcers and the Australian Wound Management Association. They will be approached by email and sent a nominal group participation information sheet and asked if they would be interested in participating in the research. This will be followed up by further email correspondence or a telephone discussion if required by the potential participants where they have any questions he/ she would like the researcher to answer regarding the implications of the research. After this should they wish to participate they will be asked to provide consent by returning a Word Document containing their electronic signature. They will be free to withdraw their participation at any time including before, during or after nominal group meetings and before, during or after questionnaire completion.

7.2 Wider Consultation Participants

Wider participants will volunteer their participation in the study in response to a general advert. Professional organisations will be approached and their associated journal editors and asked if they are able to advertise the research through their email contacts lists and journals. In addition, flyers and posters will be used at relevant conferences subject to organisational approval. The research will be advertised through a simple email communication, journal advertisements and presentations to professional/network groups Professional organisations including the UK Tissue Viability Society, European Pressure Ulcer Advisory Panel, the US National Pressure Ulcer Advisory Panel, Japanese Society of Pressure Ulcers and the Australian Wound Management Association. They will be approached by email correspondence through their usual ‘contact us’ mechanism and at no time will access to organisational membership be provided to the research team. Direct communication with members will be undertaken by the respective organisations using their local policies and procedures. Advertising materials will include a brief description of the study and a web link to the web-based survey platform which will host the participant information sheets, the summary PU risk factor systematic review and the questionnaire. Wider participants will be free to withdraw their participation at any time including during and after questionnaire completion.

8 DATA COLLECTION

8.1 Questionnaire Data Collection

Questionnaires will be completed via a commercial online survey platform. Nominal group participants and wider consultation participants will be sent an email link to the web-based questionnaire with supporting evidence and user friendly instructions of how to complete the questionnaire, as well as the timescale within which this should be undertaken. Following guidance from the HTA (2001) the questionnaire will be developed to comprise of generic risk factor stem questions preceded by related specific questions. The response options will utilise a 9 point Likert scale where 1 indicates strong disagreement and 9 indicates strong agreement, as well as a don't know option. The questionnaires will be tested prior to launch.

8.2 Nominal Group Meeting Data Collection

Nominal Group meetings will be observed, audio-taped and transcribed to allow thematic analysis of issues affecting final ratings.

9 STATISTICAL CONSIDERATIONS

Statistical analysis is the responsibility of the project lead. The analysis plan outlined in this section will be reviewed and a final statistical analysis plan will be written before any data summaries or analyses are performed. The analysis plan will be written in accordance with current CTRU Standard Operating Procedures and will be finalised and agreed by the following people: the study Statistician and Supervising Statistician, the Chief Investigator and the project lead. Any changes to the final analysis plan and reasons for change will be documented.

Nominal group and wider group participant ratings will be calculated by using the median response for each factor. Factors will be rated on the nine point Likert scale where 1 indicates strong disagreement and 9 indicates strong agreement. The extent of within group agreement for each group will be measured using the mean absolute deviation from the median. Participant demographics for both the nominal group and wider participants will be summarised using simple descriptive statistics.

10.2 Ethical Considerations

This study will recruit PU experts and clinicians. The related ethical issues are minimal and mainly relate to the time taken to complete questionnaire and/or attend audio-taped Nominal Group Meetings. There are no other forseen risks to participants. Informed consent will be obtained prior to nominal group participation in the study. The right of a potential participant to refuse without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons.

The study will be submitted to and approved by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC). The CTRU will provide SHREC with a copy of the final protocol, participant information sheets, consent forms and all other relevant study documentation.

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Appendix 17 Consensus study pressure ulcer Minimum Data Set nominal group participant information sheet

Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PU-MDS) and Pressure Ulcer Risk Assessment Framework (PURAF) Study

PU-MDS NOMINAL GROUP PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The purpose of this study is to agree a Pressure Ulcer Minimum Data Set (PU-MDS) and develop an evidence based Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice. This information sheet relates to the PU-MDS element of the study.

Why have I been chosen?

You have been invited to be a member of the Nominal Group because of your subject expertise, which is relevant to the assessment or measurement of pressure ulcer risk factors.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and asking any questions you may have. If you wish to participate you will be asked to provide consent by returning a Word Document with your electronic signature. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after nominal group meetings and before, during or after

questionnaire completion, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis. However, if you do not want your existing data from nominal group meetings or completed questionnaires to be used you can inform the researcher and this data will be destroyed and excluded from the study.

What does Nominal Group Membership involve?

If you agree to take part in the study, you will be required attend two meetings over a 12- 18 month period. Standard rate travel expenses will be reimbursed. The meetings will involve 12-14 academic or healthcare experts from a number of countries and will include in-depth discussions and debate about the factors for inclusion in a PU-MDS. Each meeting will last approximately 3.5 hours and will include refreshments and comfort breaks. The meetings will be led by trained facilitators and will be audio-taped and transcribed to allow thematic analysis of the meeting to occur. You will also be required to read a pressure ulcer systematic review summary report, comment on the content of consensus questionnaires and to complete two web-based consensus questionnaires.

Within the questionnaire you will also be asked to provide anonymous demographic data including: age, gender, nationality, area of expertise, role and sector i.e. university, community or acute hospital to allow the nominal group characteristics to be described. The summary report will take approximately 30 minutes to read and each questionnaire will take approximately 15 minutes to complete. Further email and telephone correspondence may also be required.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and this may involve you travelling for meetings.

What are the possible benefits of taking part?

You will be contributing to the development of a PU-MDS which will facilitate the interpretation and further use of pressure ulcer research data and meta-analysis. This will contribute to the development of an evidence based PURAF which could lead to improvements in patient care. Nominal group members will be listed as contributors for the main study publication, subject to your agreement. The researcher will write to you prior to

publication to ask you about this. If you agree to this you will be asked to complete a short form indicating that you agree to be listed as a contributor.

Will my taking part be kept confidential?

As part of the nominal group your identity would be apparent to other group members due to the face to face meetings but your questionnaire responses would be anonymised before being presented to the nominal group or being detailed in any reports. Your individual responses would not be revealed by the Clinical Trials Research Unit (CTRU). However, whilst under no obligation to do so, you would be free to share this with the group should you wish to.

All information collected will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. Where personal data is provided this will be stored separately to questionnaire data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. Anonymous questionnaire responses will be held on the secure web-based survey platform and will only be accessible by the web-based survey provider and the CTRU research team on a password protected restricted access database. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the CTRU at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further information and contact details

If you have any questions please contact:

Susanne Coleman
PU-MDS and PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If you wish to participate please provide consent by returning the Word Document (attached in the introductory email) with your electronic signature.

Appendix 18 Consensus study pressure ulcer Minimum Data Set nominal group consent form

Participant Study Number: *Office use only*	Participant initials:

PU-MDS NOMINAL GROUP PARTICIPANT CONSENT FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PUMDS) and Pressure Ulcer Risk Assessment Framework (PURAF) Study

The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I confirm that I have read and understand the information sheet dated (insert date of SHREC approval and information sheet version number) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
I agree to allow any information or results arising from the study to be used for training and developing new research.	
I understand that my questionnaire data may be looked at by responsible individuals from the study office where it is relevant to my taking part in the study. I give permission for these individuals to have access to my information and questionnaire data.	
I consent to the storage including electronic, of personal information (name, contact details and place of work) which will be used by the researcher for on-going contact with me for the purposes of this study only. I understand that my completed questionnaire data will remain anonymous.	
I consent to being audio-taped in nominal group meetings.	
I agree to take part in this study	
Participant Name: Participant Electronic Signature: Date:	

Thank you for agreeing to take part in this study.

Appendix 19 Consensus study Pressure Ulcer Risk Assessment Framework nominal group participant information sheet

PURPOSE

Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PU-MDS) and
Pressure Ulcer Risk Assessment Framework (PURAF) Study

PURAF NOMINAL GROUP PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The purpose of this study is to agree a Pressure Ulcer Minimum Data Set (PU-MDS) and develop an evidence based Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice. This information sheet relates to the PURAF element of the study.

Why have I been chosen?

You have been invited to be a member of the Nominal Group because of your subject expertise, which is relevant to the assessment or measurement of pressure ulcer risk factors.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and asking any questions you may have. If you wish to participate you will be asked to provide consent by returning a Word Document with your electronic signature. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after nominal group meetings and before, during or after questionnaire completion, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis. However, if you do not want your existing

data from nominal group meetings or completed questionnaires to be used you can inform the researcher and this data will be destroyed and excluded from the study.

What does Nominal Group Membership involve?

If you agree to take part in the study, you will be required attend two meetings over a 12- 18 month period. Standard rate travel expenses will be reimbursed. The meetings will involve 12-14 national and international academic or healthcare experts and will include in-depth discussions and debate about the factors for inclusion in a PURAF. Each meeting will last approximately 3.5 hours and will include refreshment and comfort breaks. The meetings will be led by trained facilitators and will be audio-taped and transcribed to allow thematic analysis of the meeting to occur. You will also be required to read a pressure ulcer systematic review summary report, comment on the content of consensus questionnaires and to complete two web-based consensus questionnaires.

Within the questionnaire you will also be asked to provide anonymous demographic data including: age, gender, nationality, area of expertise, role and sector i.e. university, community or acute hospital to allow the nominal group characteristics to be described. The summary report will take approximately 30 minutes to read, and each questionnaire will take approximately 15 minutes to complete. Further email and telephone correspondence may also be required.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and this may involve you travelling for meetings.

What are the possible benefits of taking part?

You will be contributing to the development of an evidence based PURAF which could lead to improvements in patient care. Nominal group members will be listed as contributors for the main study publication, subject to your agreement The researcher will write to you prior to publication to ask you about this. If you agree to this you will be asked to complete a short form indicating that you agree to be listed as a contributor.

Will my taking part be kept confidential?

As part of the nominal group your identity would be apparent to other group members due to the face to face meetings but your questionnaire responses would be anonymised before being presented to the nominal group or being detailed in any reports. Your individual responses would not be revealed by Clinical Trials Research Unit (CTRU). However, whilst under no obligation to do so, you would be free to share this with the group should you wish to.

Information will be handled, processed, stored, and destroyed in accordance to the Data Protection Act 1998. Your personal data including your name, contact details and place of work will be stored separately to questionnaire data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. Anonymous questionnaire responses will be held on the secure web-based survey platform and will only be accessible by the web-based survey provider and the CTRU research team on a password protected restricted access database. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the CTRU at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further information and contact details

If you have any questions please contact:

Susanne Coleman
PU-MDS and PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If you wish to participate please provide consent by returning the Word Document (attached in the introductory email) with your electronic signature.

Appendix 20 Consensus study Pressure Ulcer Risk Assessment Framework nominal group consent form

Participant Study Number: *Office use only*	Participant initials:

PURAF NOMINAL GROUP PARTICIPANT CONSENT FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PUMDS) and Pressure Ulcer Risk Assessment Framework (PURAF) Study

The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I confirm that I have read and understand the information sheet dated (insert date of SHREC approval and information sheet version number) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
I agree to allow any information or results arising from the study to be used for training and developing new research.	
I understand that my questionnaire data may be looked at by responsible individuals from the study office where it is relevant to my taking part in the study. I give permission for these individuals to have access to my information and questionnaire data.	
I consent to the storage including electronic, of personal information (name, contact details and place of work) which will be used by the researcher for on-going contact with me for the purposes of this study only. I understand that my completed questionnaire data will remain anonymous.	
I consent to being audio-taped in nominal group meetings.	
I agree to take part in this study	
Participant Name: Participant Electronic Signature: Date:	

Thank you for agreeing to take part in this study.

Appendix 21 Consensus study pressure ulcer Minimum Data Set wider consultation participant information sheet

PURPOSE

Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PU-MDS) and
Pressure Ulcer Risk Assessment Framework (PURAF) Study

WIDER CONSULTATION PU-MDS PARTICIPANT INFORMATION SHEET

This is an invitation to take part in the development of a Pressure Ulcer Minimum Data Set. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve.

What is the purpose of this part of the study?

The purpose of this study is to agree a Pressure Ulcer Minimum Data Set (PU-MDS: a list of the data that should be collected in all settings to allow clinicians to compare patient groups and the effects of treatment).

Why have I been chosen?

We have identified that you are a person with clinical and/or academic expertise and experience in pressure ulcers.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and visiting the CTRU website (insert link) or contacting the study project lead (detailed below) for more information if needed. Should you decide to participate you are free to withdraw at any time, without giving a reason. If you decide to withdraw during data entry on the web-based survey platform. your questionnaire response will be incomplete. Incomplete questionnaires will be destroyed and not used in the final study analysis. If you have fully completed the questionnaire and wish to withdraw consent for your data to be used, the study data will be

destroyed, subject to provision of your study ID number which will be issued to you on completion of the questionnaire.

What does it involve?

If you agree to take part in the study, you will be invited to read a pressure ulcer risk factor systematic review summary report and complete a web-based questionnaire relating to factors for inclusion in a Pressure Ulcer Minimum Dataset. Reading the systematic review summary report will take about 30 minutes. Completing the questionnaire after that will take about 15 minutes. You will also be asked to tell us a little bit about you - your age, gender, nationality, area of expertise and current post and sector i.e. university, community or acute hospital. We do not require your name.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time to complete the web-based questionnaire.

What are the possible benefits of taking part?

You will be contributing to the development of a Pressure Ulcer Minimum Data Set which will facilitate the interpretation and further use of pressure ulcer research data. It will also inform the development of an evidence based Pressure Ulcer Risk Assessment Framework. We hope that you will find the systematic review summary report of pressure ulcer risk factors of interest.

Will my taking part be kept confidential?

Information will be handled, processed, stored, and destroyed in accordance to the Data Protection Act 1998. If you choose to provide your contact details to allow the researcher to contact you about the results of the study, these will be stored separately to questionnaire data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. Anonymous questionnaire responses will be held on the secure web-based survey platform and will only be accessible by the web-based survey provider and the CTRU research team on a password protected restricted access database. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds. The University of Leeds is acting as the study sponsor. This is a part of a programme of research on pressure ulcers funded by the NHS National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further Information and Contact Details

If you would like more information about THIS STUDY contact:

Susanne Coleman
PU-MDS and PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If after considering the above information you wish to participate please go to page two of this link to complete the questionnaire. If not, thank you for considering taking part: please close your browser window to leave the web link.

Appendix 22 Consensus study Pressure Ulcer Risk Assessment Framework wider consultation participant information sheet

PURPOSE

Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PU-MDS) and
Pressure Ulcer Risk Assessment Framework (PURAF) Study

WIDER CONSULTATION PURAF PARTICIPANT INFORMATION SHEET

This is an invitation to take part in the development of a Pressure Ulcer Risk Assessment Framework. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve.

What is the purpose of this part of the study?

The purpose of this study is to agree a Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice.

Why have I been chosen?

We have identified that you are a person with clinical and/or academic expertise and experience in pressure ulcers.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and visiting the CTRU website (insert link) or contacting the study project lead (detailed below) for more information if needed. Should you decide to participate you are free to withdraw at any time, without giving a reason. If you decide to withdraw during data entry on the web-based survey platform your questionnaire response will be incomplete. Incomplete questionnaire will be destroyed and not used in the final study analysis. If you have fully completed the questionnaire and wish to withdraw consent for your data to be used, the study data will be destroyed, subject to provision of your study ID number which will be issued to you on completion of the questionnaire.

What does it involve?

If you agree to take part in the study, you will be invited to read a pressure ulcer risk factor systematic review summary report and complete a web-based questionnaire relating to factors for inclusion in a Pressure Ulcer Risk Assessment Framework. Reading the systematic review will take about 30 minutes. Completing the questionnaire after that will take about 15 minutes. You will also be asked to tell us a little bit about you - your age, gender, nationality, area of expertise and current post and sector i.e. university, community or acute hospital. We do not require your name.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time to complete the web-based questionnaire.

What are the possible benefits of taking part?

You will be contributing to the development of a Pressure Ulcer Risk Assessment Framework which could lead to improvements in patient care. We hope that you will find the systematic review of pressure ulcer risk factors of interest.

Will my taking part be kept confidential?

Information will handled, processed, stored, and destructed in accordance to the Data Protection Act 1998. If you choose to provide your contact details to allow the researcher to contact you about the results of the study, these will be stored separately to questionnaire data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. Anonymous questionnaire responses will be held on the secure web-based survey platform and will only be accessible by the web-based survey provider and the CTRU research team on a password protected restricted access database. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds. The University of Leeds is acting as the study sponsor. This is a part

of a programme of research on pressure ulcers funded by the NHS National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further Information and contact details

If you would like more information about THIS STUDY contact:

Susanne Coleman
PU-MDS and PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
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Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If after considering the above information you wish to participate please go to page two of this link to complete the questionnaire. If not, thank you for considering taking part: please close your browser window to leave the web link.

Appendix 23 Initial draft Risk Assessment Framework with underpinning Minimum Data Set

Screening for all patients

Mobility Status (tick applicable)	Yes	No		**PU Status** (tick applicable)	Yes	No
Does the patient walk without help?				Current PU (category ≥ 1)?		
Does the patient change position?				Reported history of PU?		

Ticks in **all un-shaded** boxes → Currently not at risk. Advise patients of PU risk factors → Reassess if condition changes and at locally specified times

Ticks in **any shaded** boxes proceed to full assessment

Full Assessment for some patients

Immobility
General Immobility Descriptors (tick applicable to patient)
Bedfast
chairfast
Walks with assistance:
Frequency and Magnitude of Movement

Frequency of position changes (circle applicable category)	*Where the 2 meet indicates level of risk related to immobility*	**Magnitude of independent movement** (relief of pressure areas). Circle applicable category		
		Doesn't move	**Slight position changes**	**Major position changes**
	Doesn't move	At risk	N/A	N/A
	Moves occasionally	N/A	At risk	At risk
	Moves frequently	N/A	At risk	Potentially at risk

Sensory Perception	**Yes**	**No**
Does the patient feel and respond appropriately to discomfort from pressure		

Skin Site	**Vulnerable Skin** e.g. redness, dryness, paper thin (tick all applicable)	**NPUAP/ EPUAP PU Category**
Sacrum		
L Buttock		
R Buttock		
L Ischial		
R Ischial		
L Hip		
R Hip		
L Heel		
R Heel		
L Ankle		
R Ankle		
L Elbow		
R Elbow		
Other		

History of PU	**NPUAP/ EPUAP Category**	**Scar** (tick if app)
Site:		
Site:		

Presence of other PU Risk Factors (tick all applicable)	**Yes**	**No**
Diabetic		
Nutrition: Unplanned weight loss		
Poor nutritional intake		
Low BMI		
High BMI		
Perfusion: Conditions affecting central circulation e.g. shock, heart failure, hypotension		
Conditions affecting peripheral circulation e.g. peripheral vascular/arterial disease		

Tick applicable	**No**	**Frequent (1 or 2 times a day)**	**Constant**
Moisture: due to perspiration, urine, faeces or exudate			

Pathway allocation

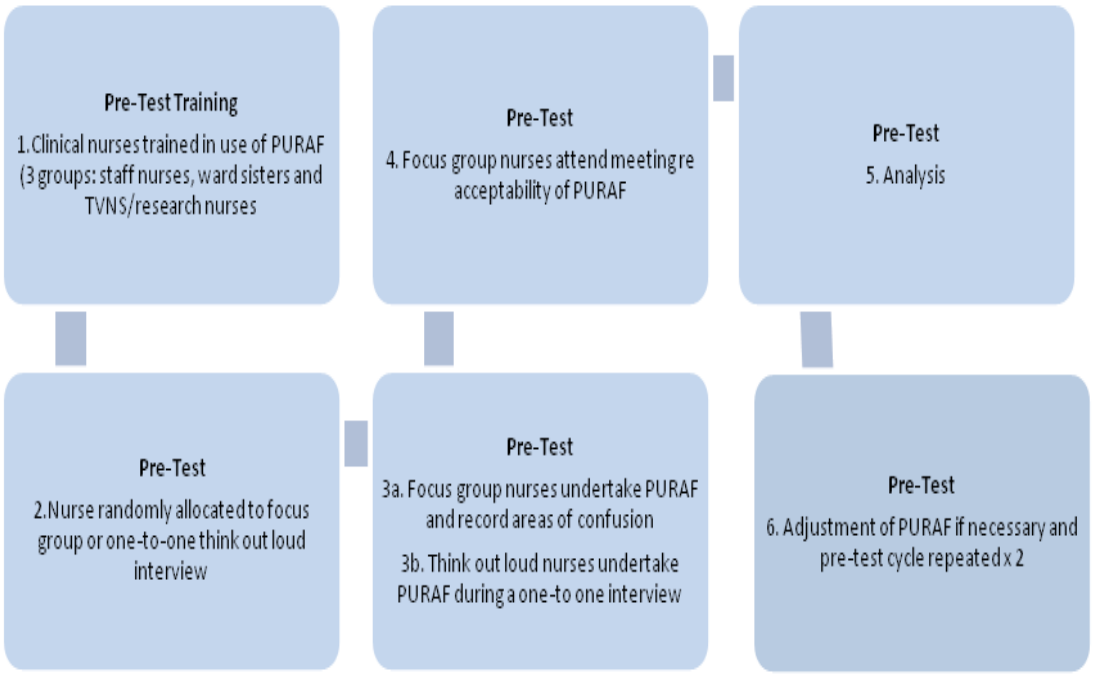
- → Not at risk pathway
- → Primary prevention pathway (at risk)
- → Secondary prevention and treatment pathway (pressure ulcer category 1 or above or scarring from previous pressure ulcer)

N/A, not applicable; PU, pressure ulcer. Reprinted from Coleman S, Nelson EA, Keen J, Wilson L, McGinnis E, Dealey C, *et al.* Developing a pressure ulcer risk factor minimum data set and risk assessment framework. *J Adv Nurs* 2014;**70**:2339–52.[126]

Appendix 24 Pressure Ulcer Risk Assessment Framework pre-test study reduced format protocol

NB: This study protocol (version 1, dated 31 January 2012) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request

3 FLOW DIAGRAM PRE-TEST



5.3 PRESSURE ULCER MINIMUM DATA SET (PU-MDS) and PRESSURE ULCER RISK ASSESSMENT FRAMEWORK (PURAF)

Work to review current risk assessment practice has been taken forward as part of the Pressure UlceR Programme Of ReSEarch (PURPOSE) - a programme of research funded by the National Institute for Health Research (RP-PG-0407-10056).

We are developing a Pressure Ulcer Minimum Data Set (PU-MDS) which will be incorporated into a Pressure Ulcer Risk Assessment Framework (PURAF) to support risk assessment in clinical practice. The development stages are detailed in Figure 1.

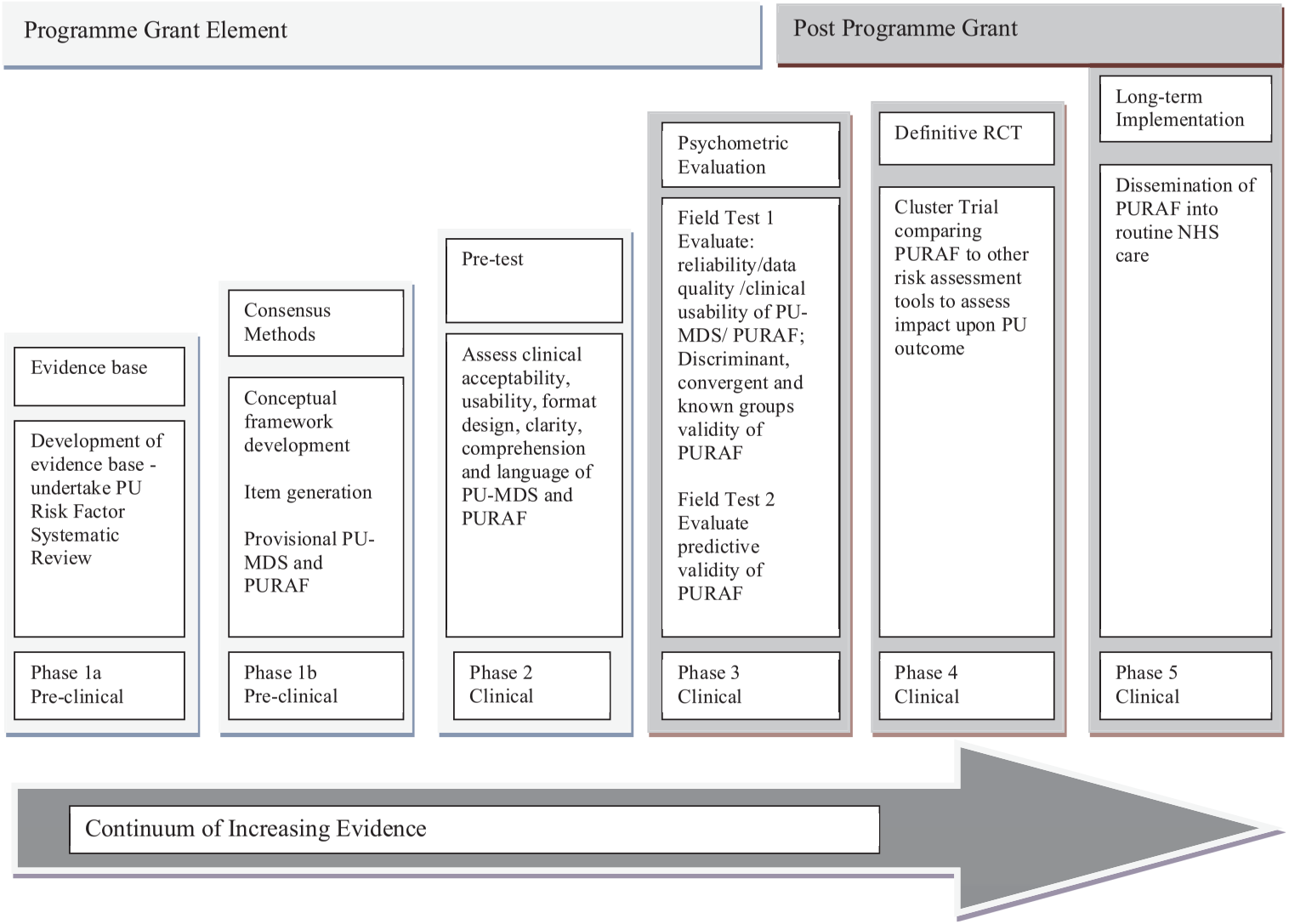


Figure 1: PhD Programme – Based on an Adapted Complex Intervention Framework (MRC 2000)

The development and evaluation of PU-MDS and PURAF has five phases. Phase 1 has involved a systematic review of epidemiological studies identifying risk factors associated with PU development (Nixon, Coleman and Gorecki et al unpublished) and a Consensus Study. The Consensus Study has utilised structured consensus methods involving an international expert nominal group and wider Delphi consultation, drawing upon the systematic review as well as wider scientific evidence, results from other PURPOSE projects (including a pain cohort study, a severe PU study and quality of life work (PU-QOL), and the experience of experts in the field to ensure face and content validity of a conceptual map and provisional PU-MDS and PURAF for use in clinical practice, by March 2012.

Phase 2, the pre-test will assess the acceptability, usability, format, design, clarity, comprehension and language of the preliminary PU-MDS and PURAF. Phase 3 will evaluate the psychometric properties of the final PU-MDS and PURAF, and comprises 2 stages: Field Test 1 will assess the reliability, data completeness, discriminant validity, convergent validity, known groups validity and clinical usability. Field Test 2 will evaluate the predictive validity of the PURAF in a prospective cohort. Phase 4 will assess the effectiveness of PURAF compared to 'standard care' in the prevention of PUs, prior to widespread NHS implementation in Phase 5.

This protocol outlines the methods for the Phase 2 Pre-test.

6 AIM AND OBJECTIVES

The aim of the pre-test is to assess the acceptability, usability, format, design, clarity, comprehension, language and data completeness of the preliminary PU-MDS and PURAF.

7 PRE-TEST METHODS

7.1 Design

Cognitive pre-testing methods will be used to indicate how clinical nurses interpret questions, response categories and instructions relating to using the preliminary PURAF (Colins 2003). The pre-test phase will incorporate PURAF training, focus groups and 'think out loud' interviews. It is anticipated that focus groups of nurses in similar roles would facilitate greater understanding of the usability of the PURAF, and would benefit from the proposed advantages of the method, allowing group members to "spark ideas off one another" which

may lead to greater disclosure (McColl 2005). However, the possible disadvantage of more vocal participants dominating discussions will be carefully counteracted by affective facilitation. Furthermore, some one-to-one think out loud interviews (Willis 2005) will also be undertaken to allow the researcher to identify specific areas where there are problems within the PURAF, which may be resolved by modification.

The Pre-test will involve nurses from a large acute Teaching Hopsital Trust, a District General Hospital and two Primary Care Trusts. We estimate that approximately 3 focus groups and 12 think out loud interviews will be needed to reach saturation (no new issues arising). As this is dedicated research activity outside of clinical hours, payment will be made to participants and this is detailed in the Participant Information Leaflet.

7.2 Eligibility of Nurses

Purposive sampling will be undertaken to ensure that Tissue Viability Nurses and Registered Nurses (Staff Nurses and Sisters) from hospital and community settings are recruited from each of the 4 participating sites. Potential participants will include those who:

- have an interest in tissue viability (for example a link nurse or member of a local PU or wound care working group)
- have commitment to attend the training session and participate in a focus group or one-to-one inteview.

7.3 Recruitment and consent

The Local Principal Investigator or a Tissue Viability Clinical Research Nurse will invite nurses to participate in the study via invitation letters and presentations to their local link nurse/pressure ulcer/wound care groups. For those who express an interest in participating in the study the Local Principle Investigator or Tissue Viability Clinical Research Nurse will explain what the study involves, provide the nurse with the written information sheet and answer any questions regarding the study. Those who fullfill the eligibility criteria and agree to take part will provide informed written consent prior to participation in the study and complete a researcher contact form to allow arrangements for the training and group session to be undertaken.

7.4 Pre-test data collection

The pre-test will comprise three sessions. Each session will comprise PURAF training, a focus group and think out loud interviews. Each session will involve 8-12 nurses from participating sites, who will be grouped by job role (Staff Nurse, Sister/Charge Nurse and TVNS/Research Nurse). The sessions will be held away from the clinical setting. Grouping the nurses in relation to their role will ensure that those participating in the focus group are similar in relation to job roles, as heterogeneous groups can lead to inhibition in raising issues that do not seem to be shared by others (McColl 2005) Furthermore, having nurses from different centres will minimise familiarity which can lead to participants relying on 'taken for granted' assumptions (McColl 2005). Each session will include training in the use of the PURAF followed by participants attending either a focus group or a one-to-one think out loud interview. Participants will be randomly allocated to either the focus group or one-to-one think out loud interview, prior to attending the PURAF session.

7.5 PURAF training

The nurses will be trained in the use of the PURAF: this will involve a short presentation and a member of the project team demonstrating how to use PURAF with a simulated patient. Each nurse will then complete the PURAF using a specific case study via vignettes that will be accompanied by photographs of pressure areas and ulcers. The vignettes will be appropriate to the nurses area of practice (i.e. community nurses will use vignettes of community patients). The vignettes will be co-developed by the project lead, the project team and members of PURSUN (Pressure Ulcer Research Service User Network) to ensure they are realistic and clinically relevant. Nurses will be encouraged to ask questions throughout the training session. It is recognised that group training may contaminate the discussions of the focus group and think out loud interviews, therefore detailed field notes of the training session will be recorded by a co-facilitator.

7.6 Focus group

The 4-8 nurses (Kitzinger 1995) assigned to the focus group will be asked to complete the PURAF again, using a vignette relevant to their area of practice prior to the focus group meeting. Nurse participants will be encouraged to highlight any areas which they find confusing on the PURAF documentation form. The co-facilitator will assess data completeness and list areas where data items have not been completed or not completed as required, as well as areas noted by the nurses as confusing.

Following this the focus group meeting will convene to discuss the use of the PURAF. The moderator will promote group interaction and guide discussions around a topic guide which will incorporate the data completeness assessment. This will consider the usability and any areas of confusion regarding the use of the PURAF. The meeting will be moderated by the researcher and a co-facilitator and will be audio-recorded.

7.7 Think out loud interviews

Up to four nurses from each session will be assigned to the one-to-one think out loud interview. Each nurse will be asked to complete the PURAF again using a vignette case study appropriate to their area of practice in the presence of the researcher. The researcher will be present to encourage the nurse to vocalise their thoughts as they complete the PURAF (see topic guide appendix 5). This will allow specific issues relating to difficulty in interpreting or confusion about aspects of the PURAF to be identified. The interview will be audio-recorded.

7.8 Data analysis

The focus group meetings and the think out loud interviews will be audio-recorded and transcribed to allow thematic analysis of issues relating to the PURAF. The emphasis will be on identifying dominant trends across the focus groups and think out loud interviews which impact on the application of the PURAF in clinical practice. Following this, adjustments in relation to the wording and the format of the PURAF may be made informing the next stages of the study. The analysis and adjustments will be made soon after each focus group and think out loud interviews, informing the PURAF used in subsequent groups in an iterative process.

Participant demographics data will be summarised using simple descriptive statistics. Data completeness of the PURAF will be assessed by missing data for data items and risk categories using simple descriptive statistics (computing the percentage of missing data for each item) and areas of confusion will be listed.

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This study will recruit Registered Nurses. The related ethical issues are minimal and mainly relate to the time taken to attend the PURAF training and audio-taped focus groups or one-to-one think out loud interviews. There are no other forseen risks to participants. Informed

consent will be obtained prior to participation in the study. The right of a potential participant to refuse without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons

The study will be submitted to and approved by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC). The CTRU will provide SHREC with a copy of the final protocol, participant information sheets, consent forms and all other relevant study documentation.

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Appendix 25 Pressure Ulcer Risk Assessment Framework pre-test study participant information sheet

Pressure UlceR Programme Of ReSEarch

The Pressure Ulcer Risk Assessment Framework (PURAF) Pre-Test Study

NURSE PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The clinical guidelines and policies in place in the NHS focus on risk assessment as being the key to prevention of PUs but risk assessment tools have not been updated for decades. While existing tools offer some structure to PU risk assessment they were developed in the 1970-80s through expert opinion and outdated literature reviewing methods when the evidence was limited. The preliminary PURAF (Pressure Ulcer Risk Assessment Framework) was developed following a systematic review of pressure ulcer risk factors and a consensus study involving international experts in the pressure ulcer field to establish what elements need to be included in pressure ulcer risk assessment. The purpose of this study is to assess the acceptability of the preliminary PURAF amongst nurses in relation its clarity and ease of use.

Why have I been chosen?

You have been invited to participate in this study as you are a practising Registered Nurse who is involved with the planning and delivery of pressure area care.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide after reading this information sheet and asking any questions you may

have. If you wish to participate you will be asked to provide informed written consent. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after the PURAF training, focus group or one-to-one interview, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis.

What does the study involve?

If you agree to take part in the study, you will be required attend a 4 hour PURAF session. The session will incorporate training in the use of the PURAF which will be followed by your participation in either a focus group meeting or one-to-one interview. It will involve you travelling to the venue in Leeds and standard rate travel expenses will be reimbursed.

The training will involve 8-12 other nurses in similar roles to yourself and will involve the researcher explaining how to use the PURAF and demonstrating this with a simulated patient (an actor taking on the role of a patient). You will then be asked to practice using the PURAF with a training case study relevant to your area of practice and photographs of pressure ulcers/areas, noting any areas of confusion on the PURAF form.

Following training you will then participate in either the focus group with approximately 4-8 other nurses or a one-to-one interview with the researcher. Allocation to the focus group and one-to-one interview will be done using randomisation in advance of the session.

If you are assigned to the focus group you will be asked to complete the PURAF again using another case study before the focus group meeting; you will be encouraged to highlight any areas which you find confusing on the PURAF documentation form which will inform the discussions of the focus group meeting. This is not a test and there are no 'right or wrong' answers. At the focus group meeting you will be invited to discuss your thoughts about using the PURAF in a group setting. It is anticipated that working in a group may spark further discussion and highlight any issues you found difficult or unclear when using the PURAF. The focus group will be led by a trained facilitator and will be audio-taped.

If you are assigned to the one-to-one interview you will be asked to complete the PURAF again using another case study. The researcher will ask you to 'think out loud' as you complete the PURAF. This is not a test and there are no 'right or wrong' answers; it will

allow the researcher to get a better understanding of areas of the PURAF which nurses find confusing to complete. The interview will be audio-recorded.

The audio-tapes from the interview and the focus group will be transcribed to allow thematic analysis of the issues relating to PURAF. At the session you will also be asked to provide anonymous demographic data including: age, gender, nationality, role and sector i.e. community or acute hospital to allow the group characteristics to be described.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and this will involve you travelling to the session.

What are the possible benefits of taking part?

You will be contributing to the development of a PURAF which could lead to more useful nurse assessment and improvements in patient care. You would also be involved in research which would help you to develop your professional portfolio in relation to being involved in research to enhance patient care. As this is dedicated research activity outside of clinical hours, the payment of £105 (subject to deductions for national insurance and tax) will be made to participants to attend the session.

Will my taking part be kept confidential?

As part of the PURAF session your identity would be apparent to other group members due to the face to face nature of the session. Focus group and individual interview responses would not be revealed by the Clinical Trials Research Unit (CTRU).

All information collected will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. Where personal data is provided this will be stored separately to focus group and interview data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

Who has organised and sponsored the research?

The study is being organised and coordinated by the CTRU at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further information and contact details

If you have any questions please contact:

Susanne Coleman
PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If you wish to participate please provide written consent.

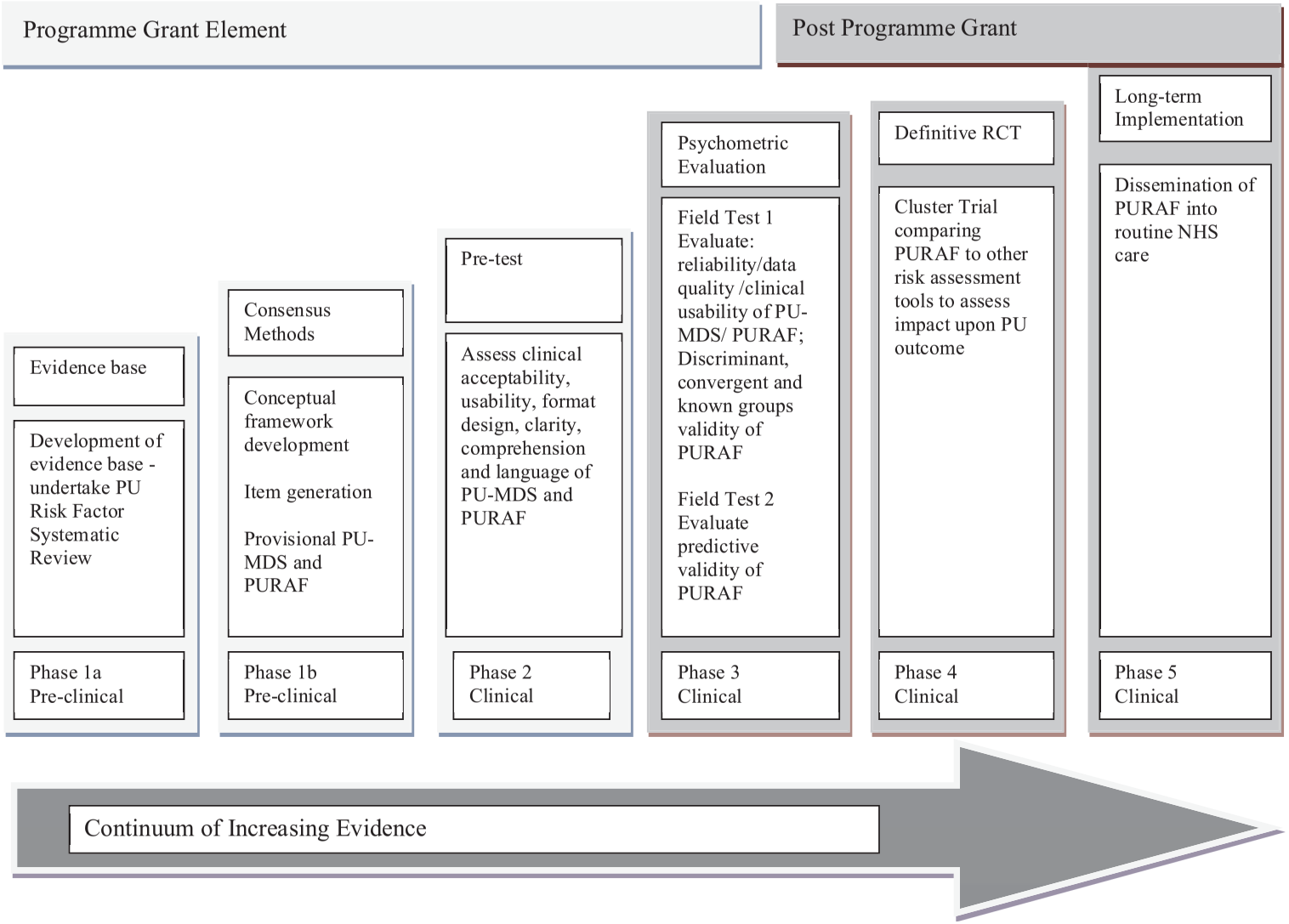

Figure 1: PhD Programme – Based on an Adapted Complex Intervention Framework (MRC 2000)

The development and evaluation of PU-MDS and PURAF has five phases. Phase 1 has involved a systematic review of epidemiological studies identifying risk factors associated with PU development (Nixon, Coleman and Gorecki et al unpublished) and a Consensus Study. The Consensus Study has utilised structured consensus methods involving an international expert nominal group and wider Delphi consultation, drawing upon the systematic review as well as wider scientific evidence, results from other PURPOSE projects (including a pain cohort study, a severe PU study and quality of life work (PU-QOL), and the experience of experts in the field to ensure face and content validity of a conceptual map and provisional PU-MDS and PURAF for use in clinical practice, by March 2012.

Phase 2, the pre-test will assess the acceptability, usability, format, design, clarity, comprehension and language of the preliminary PU-MDS and PURAF. Phase 3 will evaluate the psychometric properties of the final PU-MDS and PURAF, and comprises 2 stages: Field Test 1 will assess the reliability, data completeness, discriminant validity, convergent validity, known groups validity and clinical usability. Field Test 2 will evaluate the predictive validity of the PURAF in a prospective cohort. Phase 4 will assess the effectiveness of PURAF compared to 'standard care' in the prevention of PUs, prior to widespread NHS implementation in Phase 5.

This protocol outlines the methods for the Phase 2 Pre-test.

6 AIM AND OBJECTIVES

The aim of the pre-test is to assess the acceptability, usability, format, design, clarity, comprehension, language and data completeness of the preliminary PU-MDS and PURAF.

7 PRE-TEST METHODS

7.1 Design

Cognitive pre-testing methods will be used to indicate how clinical nurses interpret questions, response categories and instructions relating to using the preliminary PURAF (Colins 2003). The pre-test phase will incorporate PURAF training, focus groups and 'think out loud' interviews. It is anticipated that focus groups of nurses in similar roles would facilitate greater understanding of the usability of the PURAF, and would benefit from the proposed advantages of the method, allowing group members to "spark ideas off one another" which

may lead to greater disclosure (McColl 2005). However, the possible disadvantage of more vocal participants dominating discussions will be carefully counteracted by affective facilitation. Furthermore, some one-to-one think out loud interviews (Willis 2005) will also be undertaken to allow the researcher to identify specific areas where there are problems within the PURAF, which may be resolved by modification.

The Pre-test will involve nurses from a large acute Teaching Hopsital Trust, a District General Hospital and two Primary Care Trusts. We estimate that approximately 3 focus groups and 12 think out loud interviews will be needed to reach saturation (no new issues arising). As this is dedicated research activity outside of clinical hours, payment will be made to participants and this is detailed in the Participant Information Leaflet.

7.2 Eligibility of Nurses

Purposive sampling will be undertaken to ensure that Tissue Viability Nurses and Registered Nurses (Staff Nurses and Sisters) from hospital and community settings are recruited from each of the 4 participating sites. Potential participants will include those who:

- have an interest in tissue viability (for example a link nurse or member of a local PU or wound care working group)
- have commitment to attend the training session and participate in a focus group or one-to-one inteview.

7.3 Recruitment and consent

The Local Principal Investigator or a Tissue Viability Clinical Research Nurse will invite nurses to participate in the study via invitation letters and presentations to their local link nurse/pressure ulcer/wound care groups. For those who express an interest in participating in the study the Local Principle Investigator or Tissue Viability Clinical Research Nurse will explain what the study involves, provide the nurse with the written information sheet and answer any questions regarding the study. Those who fullfill the eligibility criteria and agree to take part will provide informed written consent prior to participation in the study and complete a researcher contact form to allow arrangements for the training and group session to be undertaken.

7.4 Pre-test data collection

The pre-test will comprise three sessions. Each session will comprise PURAF training, a focus group and think out loud interviews. Each session will involve 8-12 nurses from participating sites, who will be grouped by job role (Staff Nurse, Sister/Charge Nurse and TVNS/Research Nurse). The sessions will be held away from the clinical setting. Grouping the nurses in relation to their role will ensure that those participating in the focus group are similar in relation to job roles, as heterogeneous groups can lead to inhibition in raising issues that do not seem to be shared by others (McColl 2005) Furthermore, having nurses from different centres will minimise familiarity which can lead to participants relying on 'taken for granted' assumptions (McColl 2005). Each session will include training in the use of the PURAF followed by participants attending either a focus group or a one-to-one think out loud interview. Participants will be randomly allocated to either the focus group or one-to-one think out loud interview, prior to attending the PURAF session.

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Up to four nurses from each session will be assigned to the one-to-one think out loud interview. Each nurse will be asked to complete the PURAF again using a vignette case study appropriate to their area of practice in the presence of the researcher. The researcher will be present to encourage the nurse to vocalise their thoughts as they complete the PURAF (see topic guide appendix 5). This will allow specific issues relating to difficulty in interpreting or confusion about aspects of the PURAF to be identified. The interview will be audio-recorded.

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Appendix 26 Pressure Ulcer Risk Assessment Framework pre-test study consent form

Participant Study Number: *Office use only*	Participant initials:

PURAF PRE-TEST NURSE PARTICIPANT CONSENT FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

The Pressure Ulcer Risk Assessment Framework (PURAF) Pre-Test Study

The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I confirm that I have read and understand the information sheet dated (insert date of SHREC approval and information sheet version number) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	
I agree to allow any information or results arising from the study to be used for training and developing new research.	
I understand that my focus group and interview data may be looked at by responsible individuals from the study office where it is relevant to my taking part in the study. I give permission for these individuals to have access to my information and data.	
I consent to the storage including electronic, of personal information (name, contact details and place of work) which will be used by the researcher for ongoing contact with me for the purposes of this study only. I understand that my completed interview and focus group data will remain anonymous.	
I consent to being audio-taped in the focus group meeting or one-to-one meeting.	
I agree to take part in this study	
Participant Name: Participant Signature: Date:	

Thank you for agreeing to take part in this study.

Appendix 27 Pressure Ulcer Risk Assessment Framework pre-test study case studies

RAF Pre-Test Acute Sector Case Studies

Case Study 1

Trudie is a 75 year old lady who lives with her husband. She is admitted to hospital for investigations into her intermittent abdominal pain. She is active and mobile and other than intermittent abdominal pain reports being fit and well. Trudie walked on to the ward unaided. She reports no skin problems.

Case Study 2

Susan is a 21 year old student who is admitted with a severe headache. She is a keen hockey player and reports being usually fit and well. Susan refuses analgesia as it makes her feel 'strange'. She is fully mobile: due to her pain she can't get comfortable and moves from bed to chair frequently and walks to the toilet. She reports no skin problems.

Case Study 3

John is a 29 year old gentleman who is admitted with acute appendicitis. John is a keen rugby player and is normally fit and well, though he is an insulin dependent diabetic which is well controlled and he does not have peripheral neuropathy. On admission John has a lot of pain, feels generally unwell and remains in bed. He has pain relief but is fully alert. John moves around in bed independently and frequently walks to the toilet unaided. John generally has a good diet and has a muscular stocky build, but is put nil by mouth on admission and is to have an IVI put up. He has no moisture or circulation problems. The staff nurse assesses John's pressure ulcer risk as part of her admission procedures.

Case Study 4

Hilda is an 80 year old lady who is admitted to the elderly care ward following a chest infection. Hilda lives in a warden controlled flat with her 85 year old husband. Hilda has a history of COPD and previous chest infections. Hilda is usually quite active and mobile within in her home but is restricted to the distance she can walk due to breathlessness.

On admission to the ward Hilda is weak and not as mobile as usual: she is able to transfer herself but needs the aid of one nurse to accompany her when walking to the toilet as she feels unsteady. She is able to change her position independently and does when she feels uncomfortable, but is lethargic and spends most of her time in the chair. Hilda has lost her

appetite and says she has lost weight in the last 2-3 weeks and appears to be very thin and bony. She has been taking steroids and her skin appears thin and dry. She doesn't have any moisture problems and is not diabetic. The staff nurse assesses Hilda's pressure ulcer risk as part of her admission procedures.

Case Study 5

Jenny is an 80 year old married lady who is admitted to surgical ward with abdominal pain following an elective laparoscopic cholecystectomy 14 days ago. On admission she has a temperature of 39 – 40 degrees C and is very sweaty. She is being treated in a side room due to a possible infection and diarrhoea. She is 'nil by mouth' and commences IV fluids and antibiotics, though normally eats well and is a healthy weight. Jenny is given morphine as pain relief which makes her very sleepy. She is very lethargic and rests in her bed. She is able to transfer to the commode with the assistance of one nurse. She is able to change her position independently in bed but due to her lethargy doesn't very often. Prior to her recent health problems Jenny was in good health, is not diabetic and doesn't have any circulatory problems. The staff nurse assesses Jenny's pressure ulcer risk as part of her admission procedures.

Case Study 6

Joan Smith, a 72 year old lady who lives alone, has just been admitted to an acute medical ward following a stroke. Joan works part-time as a florist. She was found unconscious on the floor by her friend. It is unclear how long she had been on the floor but no one had seen her for 18 hours. Prior to having the stroke Joan's son reported she was in reasonable health and was fully mobile, though she does have hypertension which is controlled with medication. He reported that she had a good appetite, was not diabetic and didn't have any problems with her circulation.

On admission Joan is conscious but dazed and had been incontinent of urine. She has a right sided hemiplegia and is unable to walk or weight bear. Joan is presently being nursed in bed and a physio assessment is being undertaken later today. She is unable to change her position in bed. Joan is to be 'nil by mouth' until she has a swallow test, was dehydrated on admission and so has an IVI is in place. She is overweight.

Case Study 7

Joe is a 65 year old retired tool maker who has been in hospital for the last 4 days for investigations of vascular disease. He lives with his partner and until the last 6months was quite active enjoying gardening in his allotment. Joe reports that he used to be a heavy smoker but managed to stop smoking 18months ago. He has severe pain in his left calf when walking which has led to a reduction in mobility: he is able to walk short distances unaided. He has obvious poor peripheral circulation. He is if of normal build, eats a good diet and is not diabetic

On the second day of his hospital stay Joe developed a chest infection and a high temperature and felt generally unwell. He has spent the last few days mainly in bed though has walked to the toilet occasionally and is continent. While in bed he was able to change his position when uncomfortable but remained mostly in the recumbent position. The staff nurse reassesses Joe's pressure ulcer risk in response to his changing condition and in response to him reporting a sore left heel.

RAF Pre-Test Community Sector Case Studies

Case Study 1

Sally is a 19 year old student and newly diagnosed diabetic. She is visited by the Diabetic Specialist Nurse for training and support in relation to giving her own insulin. Sally leads a very active outdoor life and other than her diabetes is fit and well. She reports no skin problems.

Case Study 2

Hilda is a 70 year old lady with rheumatoid arthritis who lives with her husband. She has recently had a short hospital stay after stumbling and fracturing her humerus. Hilda normally gets about her home well often using the furniture and a walking frame when necessary (particularly outside the home). The hospital nurses were concerned that her mobility had reduced and that she needed help to walk as she couldn't use the frame due to her fractured humerus: they requested a District Nurse visit to assess her pressure ulcer risk at home.

The District Nurse visited Hilda at home on the day after her discharge from hospital. Hilda reported that other than her long-term problem of rheumatoid arthritis she was quite well and independent. She eats a balanced diet, is a normal weight and is not diabetic. She doesn't

have any circulatory problems and is continent. She acknowledged that while she had found walking in the hospital difficult this has not been a problem since she had returned home: she explained that while she was unable to use the walking frame she was able to use the furniture in her home to get around and she had lots of aids and adaptations to help her– obviously this had not been possible on the hospital ward. She reported that she had been glad to get home where she had regained her independence and was enjoying 'pottering' at home and changed her position frequently. She was also glad to be enjoying home cooked food rather than the 'hospital slop'.

Case Study 3

John is an 82 year old, retired teacher who lives in his detached bungalow on his own following the death of his wife 2 years ago. His son lives away and his daughter lives in the next town 10 miles away. John has peripheral vascular disease, is diabetic and has peripheral neuropathy. John had a recent hospital stay following a chest infection and difficulties managing his diabetes with oral medication: he is now insulin dependent. Whilst in hospital John developed a category 2 pressure ulcer on his right heel but this is now reported to be healed.

The District Nurse visits John on his return home to assess his needs and pressure ulcer risk and to administer his daily insulin. He has meals on wheels and homecare to help with food preparation, cleaning and helping him to bed. He has a good appetite and is slightly overweight. Johns neighbour brings him a paper each morning and checks he is ok. John spends most of the day in his chair, only moving when he needs the toilet and is continent. He is able to walk in his home with a walking frame but sometimes needs prompting.

Case Study 4

Eileen is a 75 year old retired secretary and is in the end stages of terminal uterine cancer. She is being cared for at home by her husband and their daughter with support from the District Nursing Team. As Eileen's condition deteriorates the District Nurse reassesses her pressure ulcer risk. Eileen is very weak and spends most of her time in bed though does get up for short periods. She has just started having a morphine syringe driver and is quite lethargic. She can independently turn over in bed but doesn't do this very often. She needs the help of another person to transfer. Eileen developed a raised temperature and was found to have a UTI for which she is having antibiotics: due to this has been incontinent of urine.

Eileen has a poor appetite and is just eating small amounts, though appears to be of normal weight. She is not diabetic and does not have any circulatory problems.

Case Study 5

Jack is an 86 year old retired builder who lives in a residential home due to dementia. The District Nurse has been called to assess his pressure ulcer risk as his condition has recently deteriorated. He has developed a chest infection which is related to swallowing difficulties. Jack needs to be fed by the carers and has recently been refusing to eat and has lost weight, though appears to be of normal weight. He is not diabetic and doesn't have any circulatory problems. He is regularly incontinent of urine and faeces. Jack spends most of his time in the chair or bed and needs 2 nurses to assist him to transfer. He can only make small independent movements when in his bed or chair. He gets very agitated at times.

Case Study 6

Beatrice is 50 years old and has primary progressive MS. Beatrice had to give up her job as a dinner lady 7 years ago when her mobility deteriorated to the point that she could no longer work. Since that time her mobility has steadily declined and got significantly worse over the last 6 months. She is now unable to walk or talk making communication very difficult. She is cared for at home (in a ground floor flat) by her husband and 2 daughters who managed quite well up until the last 6 months when she has become very dependent. Care workers come in rarely. Her husband works full time, plus extra hours to support the family as he has a poorly paid job. The family have had little advice about how to care for Beatrice as her condition has declined. After her husband visits the GP in distress saying they are struggling to cope and Beatrice is becoming sore, a District Nurse is requested to visit to assess Beatrice's care needs and her pressure ulcer risk.

Beatrice is doubly incontinent with her urinary incontinence being a constant problem. They use pads in bed, but this has been difficult as they don't have an adequate supply. She spends all her time in her single divan bed. She is unable to move independently and is not turned regularly as her daughters have not been told what to do to help her. No one inspects her skin condition regularly at home. She cannot eat properly and is losing weight, though is of normal build and is not diabetic. She doesn't have any circulatory problems. She is unable to tell anyone if she is in pain and is unable to move herself to get comfortable.

Case Study 7

Stephen is a 35 year old gentleman who was left paralysed from the waist down following a motorbike accident 10 years ago: he is a full-time wheelchair user. He lives with his partner and their son. He runs his own IT Company. Stephen eats a good diet and is a healthy weight. He does not have any circulatory problems or diabetes. He is uses intermittent catheterisation. He transfers from his chair independently. Stephen has been under a lot of pressure at work and has not been undertaking skin inspections or position changes as he was taught and has been spending long periods of time in the same position working at his desk. He has also had a recent urine infection but continued to work without taking a break. The GP was called after Stephen's wife noticed blood on the bed sheets and a District Nurse visit was requested to undertake a pressure ulcer risk assessment.

Appendix 28 Pressure Ulcer Risk Assessment Framework focus group topic guide

1. Introduction of moderators and group members by name.
2. The overall aims of the study and how the focus group contributes to this will be explained by the moderator.
3. Aims of the session – to consider the acceptability of using the Pressure Ulcer Risk Assessment Framework (PURAF) incorporating:

    i. what was liked about the PURAF
    ii. what was disliked about the PURAF
    iii. usability of the PURAF and how nurses found using the PURAF overall (were there any confusing areas)
    iv. whether nurses anticipate any problems in using the PURAF in clinical practice.

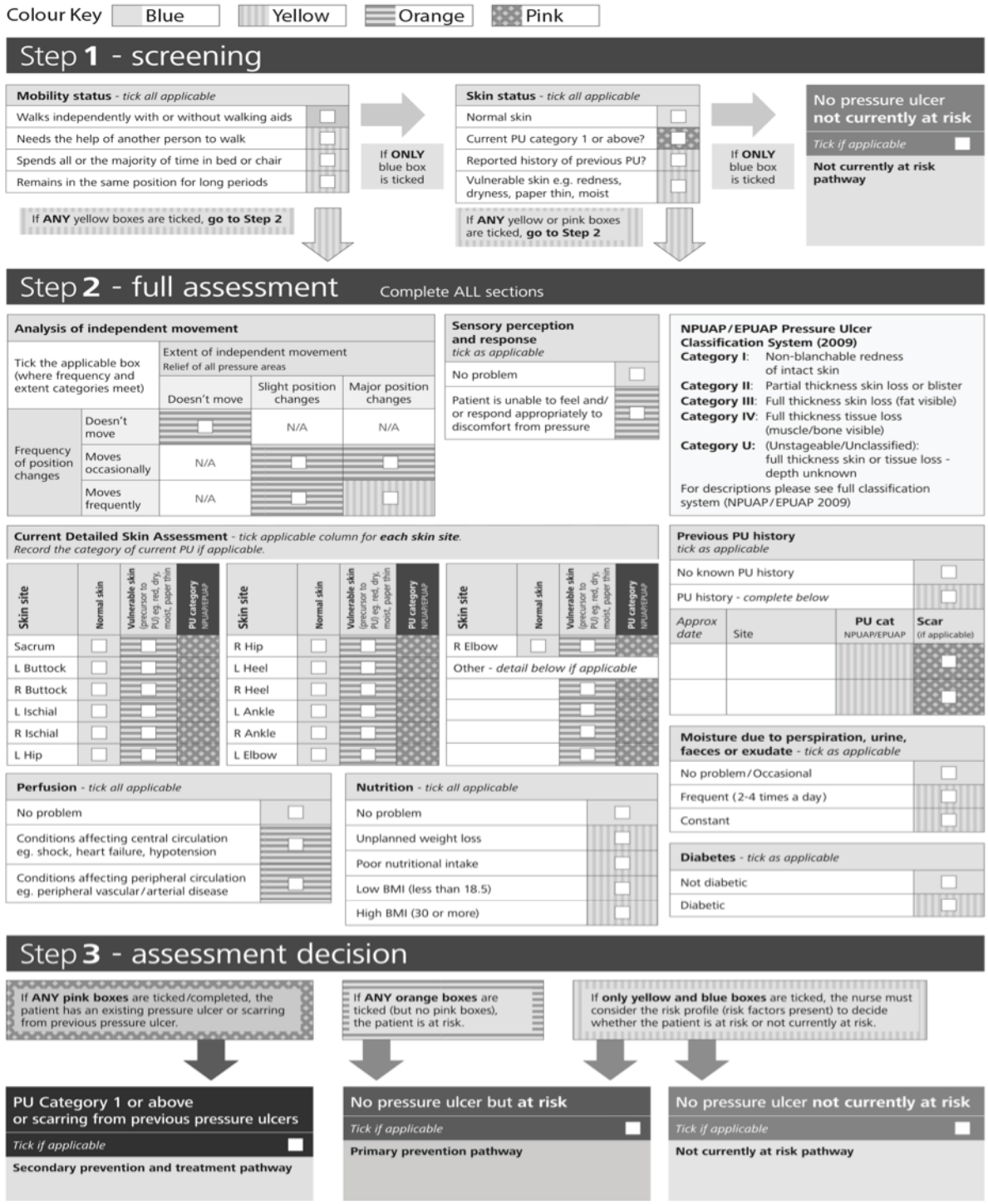
4. Ground rules – Everyone will have chance to speak and be heard. There are not right or wrong answers. The moderator will remind the group that the meeting will be audio-taped, answer any questions and confirm that everyone is happy to proceed with the meeting.
5. Ice breaker – discussion in pairs of what was liked about the PURAF and list on flip chart and group feedback.
6. Group discussion of what was disliked about the PURAF and list on flip chart.
7. Group discussion of the usability of the PURAF and how the nurses found using the framework overall (were there any confusing areas). The moderator will use the data completeness forms taken from the training element to inform discussions. Note on flip chart.
8. Group discussion of any anticipated problems with using the PURAF in clinical practice. Note on flip chart.

Appendix 29 Pressure Ulcer Risk Assessment Framework pre-test study think out loud topic guide

1. Introduction of researcher to nurse.
2. Aims of the interview are to identify any specific items that cause confusion when using the PURAF.
3. Ground rules – There are not right or wrong answers. The researcher will remind the nurse to 'think out loud' as he or she completes the PURAF. The researcher will remind the nurse that the interview will be audio-taped, answer any questions and confirm that he or she is happy to proceed with the interview.
4. The nurse completes the PURAF again using a case study with photographs and the researcher encourages the nurse to 'think out loud' as he or she does this.

Appendix 30 Preliminary Risk Assessment Framework: PURPOSE-T

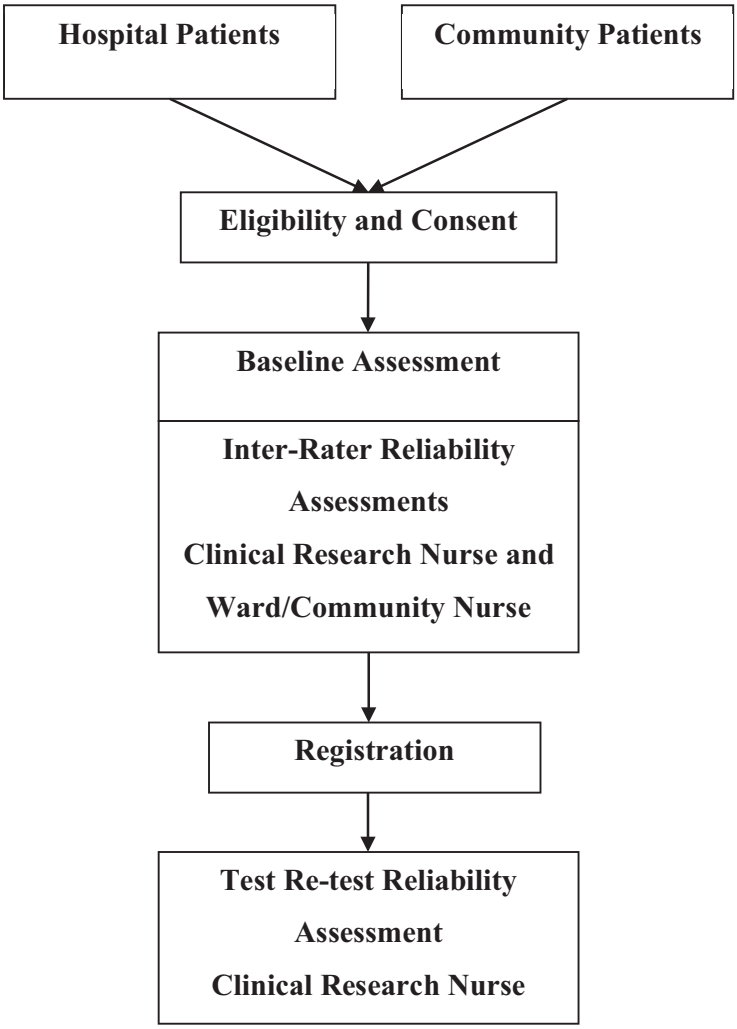
Please note that the PURPOSE-T incorporates the use of colour to aid decision-making. This version of the tool has been adapted with the colour key included. It is not intended for implementation and is not the final version of the tool.



Appendix 31 Pressure Ulcer Risk Assessment Framework field test 1 reduced format protocol

NB: This study protocol (version 3, dated 30 Oct 2012) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to serious adverse events, data monitoring, quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request

4 FLOW DIAGRAM PURAF FIELD TEST 1



6 AIM AND OBJECTIVES

The aims of Field Test 1 are to:

1. assess the inter- rater and test-retest reliability of the PURPOSE T
2. assess the convergent validity, known groups validity, data completeness and clinical usability of the PURPOSE T.

7 FIELD TEST 1 METHODS

7.1 Design

The PURPOSE T will be evaluated through field testing using observational descriptive methods. The Field Test will evaluate the PURPOSE T in relation to its inter-rater reliability, test re-test reliability, data completeness, convergent validity, known group differences and clinical usability. Appendix 2 presents full details of the tests and criteria used in the instrument evaluation.

In-patients and community nursing patients will be invited to participate. Demographic characteristics and pressure ulcer risk will be assessed for all patients. Paired assessments will be undertaken using the PURPOSE T, one by a ward/community nurse and one by a nurse from the Tissue Viability Team (TVT; Tissue Viability Nurse Consultant/Specialist/Research Nurse) with specialist tissue viability knowledge. To minimise patient burden the clinical skin assessment component of the PURPOSE T assessment will be undertaken simultaneously by both assessors, but recorded separately with blinding maintained. The other components of the assessment will be undertaken separately and each nurse will remain blind to the corresponding assessment. Finally the 'TVT nurse will reassess the patient using the PURPOSE T at a clinically appropriate timeline determined on an individual patient basis but broadly 1-7 days after the first assessment.

7.2 Description of pressure ulcer risk primary or secondary evaluation tool (PURPOSE T)

The PURPOSE T instrument has been developed to identify whether patients are 'not at risk' or 'at risk' of pressure ulcer development. It consists of 22 data items for the assessment of 6 risk factor domains (mobility, skin, nutrition, perfusion, moisture and sensory percention). 19 items are a yes/no response and 3 items are a 3 point categorical sub-scale. Completion of the

assessment framework leads to a decision about risk status. Nurses using the PURPOSE T will have completed standard training in its use. A draft of the provisional PURPOSE T which is currently being developed by a graphic designer prior to the pre-test stage (April-May 2012) is detailed in Appendix 1.

7.3 Patient eligibility

7.3.1 Inclusion criteria

Patients who meet the following inclusion criteria:

- Aged ≥ 18years
- An inpatient in the acute setting or community nursing patient in the community setting
- Give their written informed consent/verbal witnessed consent/consultee agreement
- Expected to be available for the PURPOSE T re-test

7.3.2 Exclusion criteria

- Patients in obstetric, paediatric, day case surgery or psychiatric settings(acute or community)
- Unable to provide consent/consultee agreement
- Deemed by the attending healthcare professional to be too unwell to be approached and/or complete the study assessment schedule

7.3.3 Sampling strategy

An approximate sample of 230 patients will be purposively sampled ensuring a similar number of hospital and community patients and representation of patients across 4 broad levels of risk (as defined by their mobility and PU status) as follows:

- No mobility restrictions
- Some mobility/ activity limitations
- Bedfast/chairfast
- PU category ≥1

Each ward/community nurse will identify patients on their caseload who have the above characteristics.

We will monitor patient characteristics for other key risk factors including micro and macro circulatory disease, diabetes, nutritional deficits and moisture problems and target sampling if required.

In the hospital setting, specialties (vascular, elderly, medicine, orthopaedics, oncology, surgery) and acute/elective wards will be mapped and ward nurses will be identified in all these areas, ensuring balanced representation of patients.

7.4 Recruitment and consent

Ward/community based nurses will identify suitable patients from their area of practice. A full verbal explanation of the study Patient Information Leaflet will be provided by the attending clinical staff or a member of the Tissue Viability Team (TVT; Tissue Viability Nurse Consultant/Specialist/Research Nurse) for the patient to consider. This will include detailed information about the rationale, design, and personal implications of the study. Following information provision, patients will have as long as they need to consider participation and will be given the opportunity to discuss the study with their family and other healthcare professionals before they are asked whether they would be willing to take part in the study. Assenting patients will then be invited to provide informed, written consent. Should the patient be capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member or friend of the patient, or another member of the patient's healthcare team who is not directly involved in the research study.

A record of the patient involvement in the study and consent/assent process detailing the date of consent will be documented in the patient healthcare records.

Assessment of eligibility and informed consent will be undertaken by a member of the TVT The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment.

The original consent/assent form will be retained in the Investigator Site File, a copy of the consent form will be given to the patient, a second copy filed in the patient's healthcare records and a third copy will be sent to CTRU.

7.4.1 Consultee agreement

A large proportion of patients suffering from pressure ulcers/at risk of pressure ulcers have receptive or comprehension or language difficulties. They may also have general cognitive impairment affecting their understanding and/or dementia. To ensure that the study population is representative of the clinical population assessed in the course of usual care, recruitment procedures will facilitate consultee agreement. This is important because the nature of a pressure ulcer risk assessment includes history taking and also clinical examination, both of which are impacted when patients have cognitive impairment or language difficulties. In order to assess the reliability and validity of the PURPOSE T as the basis for use in clinical practice, it is important that the study population is a representative patient population.

The assessment of capacity will relate specifically to decisions pertaining to this particular research project. Each patient will be assumed to have capacity unless it is established that they lack capacity. Ward/community based nurses identifying patients for study participation, will be asked to consider aspects of capacity before any approach to patients is made and during the information giving stage prior to consent. The TVT member will assess the patient's ability to understand what decisions they need to make and why; the consequences of the decision to participate; their ability to understand, use and retain the information related to the decision to participate and be able to communicate their decisions effectively (as specified in the Mental Capacity Act 2005). If there is any concern about capacity the ward/community based nurses/TVT member will consult further with other members of the attending clinical team and/or relative/carer/friend (as appropriate) and a decision will be made with the relative/carer/friend as to whether the patient is able to provide written consent. Where the patient is thought not to have capacity to consent, a relative, carer or friend who is interested in the patient's welfare will act as a personal consultee.

The relative/carer/friend will be involved in the information and decision making process with the patient and will advise the TVT member on their presumed wishes and feelings and Consultee Assent will be obtained on behalf of the patient. The relative, carer or friend will

be advised to set aside their own views and provide advice on the participation of the patient in the research, taking into consideration the patient's wishes and interests. Research participants will not be required to do anything which is contrary to any advance decisions or statements that have been made by them in relation to their treatment or any other matter. Advance decisions made by the patient about their preferences and wishes will always take precedence.

If, despite taking all reasonable steps, a personal consultee cannot be identified and contacted then a nominated consultee would be approached. This person would have no connection with the research project. They would be nominated by the TVT member; they would most likely be the participant's lead clinician, their GP or a member of the care team. The consultee would be provided with the information leaflet describing the research study and the role of the consultee and it would be emphasised that they are being asked to act on behalf of the participant, rather than any personal views or feelings.

It is unlikely to place a major burden on consultees as the research is a non-invasive study that has minimal burden on the participant. There are no changes in treatment relating to the study.

7.5 Registration

Patients who are both eligible for study participation and provide informed consent/consultee agreement will be registered. Informed consent for entry into the study must be obtained prior to registration. Following confirmation of informed consent/consultee agreement and eligibility patients will be registered into the study by an authorised member of staff at the study research site.

Registration will be performed centrally using the CTRU automated 24-hour telephone registration system. Authorisation codes and PINs, provided by the CTRU, will be required to access the registration system.

The following information will be required at registration:

- Patient details, including initials, gender and date of birth
- Site code for research site

- Name of person making the registration
- Confirmation of eligibility
- Confirmation of informed consent/consultee agreement

Direct line for registration +44 (0)113 343 3377

8 ASSESSMENT AND DATA COLLECTION

Assessments will be undertaken as follows:

- Baseline
  - Demographics
  - Clinical assessment
  - PURPOSE T assessment (Ward/Community Nurse) and PURPOSE T (member of TVT)
- Test-retest
  - PURPOSE T (same member of TVT who undertook the PURPOSE T assessment at baseline) at a clinically appropriate timeline determined on individual patient basis but broadly 1-3 days for hospital patients and 1-7 days community patients

8.1 Research Assessments

8.1.1 Baseline demographics

A member of the TVT will record baseline demographics information including:

- Name of NHS Trust
- NHS Facility/Service name (name of hospital/intermediate care/community nursing team)
- Type of admission/referral (e.g. elective/acute)
- *Hospital patients only* - speciality
- Initials
- Date of birth
- Gender
- Ethnicity

To enable the test-retest follow-up the TVT member will record and destroy after the visit the following information:

- Patient's NHS ID
- Patient's Hospital/Trust number (if applicable)
- *Hospital patients only* – ward number/name
- *Community patients only* – place of residence

8.1.2 Baseline clinical assessment

A member of the TVT will record baseline clinical assessment including:

- Date and time of assessments
- Braden Score (Braden and Bergstrom 1987) (Appendix 3)
- Waterlow Scale (Waterlow 1985) (Appendix 4)

Table 1 NPUAP/EPUAP Pressure Ulcer Classification System (2009)

Category	Description
Category I Non-blanchable redness of intact skin	Intact skin with non-blanchable erythema of a localised area usually over a bony prominence. Discolouration of the skin, warmth, oedema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.
Category II Partial thickness skin loss or blister	Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or sero-sanginous-filled blister.
Category III Full thickness skin loss (fat visible)	Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are *not* exposed. Some slough may be present. *May* include undermining and tunnelling.
Category IV Full thickness tissue loss (muscle/bone visible)	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often includes undermining and tunnelling.
Category U (Unstageable/ Unclassified) Full thickness skin or tissue loss – depth unknown	Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, grey, green, or brown) and/or eschar (tan, brown, or black) in the wound bed.

8.1.3 PURPOSE T assessment

- Ward/Community Nurse
    - Date and time of assessment
    - PURPOSE T including skin assessment (sacrum, buttocks, heels, hips and other) (Appendix 1)using the skin classification scale (Table 1)
- Member of TVT
    - Date and time of assessment
    - PURPOSE T including skin assessment (sacrum, buttocks, heels, hips and other) (Appendix 1) using the skin classification scale (Table 1)

8.1.4 Test re-test risk assessments

- Same TVT member that undertook the first PURPOSE T assessment (8.1.4)
    - Date and time of assessment
    - PURPOSE T including skin assessment (sacrum, buttocks, heels, hips and other) (Appendix 1)using the skin classification scale (Table 1)
    - Clinically relevant changes to condition since baseline assessment

8.2 Data collection Procedures

8.2.1 Baseline assessments

Following informed consent/relative assent and at a time convenient to the patient the TVT member will complete demographic, clinical assessments and all components of the PURPOSE T apart from the skin assessment component. This baseline assessment will involve general observation (for example of spontaneous movement), history taking, and consulting relevant sections of the medical/nursing records.

A paired ward/community nurse PURPOSE T assessment will be undertaken separately at a time convenient to the patient and close enough in time to the TVT assessment to avoid any change in clinical condition. A PURPOSE T assessment proforma will be provided to the ward/community nurse with pre-populated standard header details including patient initials, date of birth and study ID. The ward/community nurse will complete all components of the PURPOSE T apart from the skin assessment component.

To minimise patient burden and due to the transient nature of alterations to intact skin which impacts upon the reliability of the skin assessment component (Nixon et al 2005a) the Stage 2 clinical skin assessment component of the PURPOSE T assessment will be undertaken simultaneously by both the ward/community nurse and TVT member, but recorded on separate PURPOSE T proformas, with blinding maintained. This method has been successfully adopted previously in an inter-rater reliability skin assessment study (Nixon et al 2005, Nixon et al 2006).

Following blinded completion of the PURPOSE T proforma the TVT member and the ward/community nurse will separately fold and seal their copies of the completed pro-forma. The TVT member will return the sealed proforma's with the other study documentation in a sealed envelope to the Clinical Trials Research Unit and the other sealed carbonated copies of the PURPOSE T will be kept in the site file.

8.2.2 Test re-test

The TVT member who undertook the initial PURPOSE T assessment will undertake a second PURPOSE T assessment, without access to the first assessment. The length of the test re-test interval must be short enough to ensure that clinical change in the PU is unlikely to occur, but sufficiently long to ensure that respondents do not recall their responses from the first assessment. A short test re-test interval is necessary to ensure that stability per se is being evaluated, rather than clinical change in the PU during the test re-test interval, which will underestimate reliability. We anticipate that the re-test will be undertaken between 1-3 days in hospital patients and 1-7 days in community patients, after the first assessment depending upon the anticipated recovery/deterioration/stability of the patients' condition and for hospital patients, length of stay. The assessing nurse will determine the re-test date and time, with the patient at the end of the baseline assessment visit.

8.2.3 PURPOSE T Field Notes

The TVT members involved in data collection will keep field notes of their experience of using PURPOSE T in clinical practice. The field notes will be summarised and used to inform design amendments and issues of importance for implementation.

9 STATISTICAL CONSIDERATIONS

9.1 Sample size

9.1.1 Inter-rater reliability

In the study population we expect approximately 25% will be 'not at risk' and 75% 'at risk'. In a 2-rater study, the numbers of subjects required to detect a statistically significant κ (2-sided p-value ≤ 0.05) with 90% power and 75% assessed as being 'at risk', assuming a null hypothesis value for κ are given in Table 2. To establish whether the tool gives a high degree of beyond-chance agreement, we will test against a null value of 0.6. With 90% power, 199 patients will be required. To allow for withdrawal/non-compliance in paired ward/community nurse assessments of 15% we will aim to recruit 230 patients.

9.1.2 Validity assessment

No examples of formal sample size estimation methods for evaluation of screening instruments were identified in the literature. Therefore, literature relating to the psychometric evaluation of rating scales were considered. The 'rule of thumb' recommendation of 5-10 patients for every item in a questionnaire has been used to estimate the sample size of 115-230 patients (Nunnally and Bernstein 1994, Blazeby et al 2002). The proposed sample size of 230 to assess the inter-rater reliability of the instrument, with >95% TVT data compliance (based upon previous research experience), will therefore provide sufficient numbers of patients to assess the validity of the risk assessment instrurment.

Table 2 Inter-rater reliability sample size estimates

Kappa to detect	Null value	N required patients (90% Power)
0.7	0.4	114
0.7	0.5	231
0.7	0.6	793
0.8	0.4	64
0.8	0.5	103
0.8	0.6	199
0.8	0.7	536
0.9	0.4	41
0.9	0.5	58
0.9	0.6	89
0.9	0.7	159

9.2 Analysis methods

The analysis plan outlined in this section will be reviewed and a final statistical analysis plan will be written before any data summaries or analyses are performed. The analysis plan will be written in accordance with current CTRU Standard Operating Procedures. Any changes to the final analysis plan and reasons for change will be documented.

9.2.1 Inter-rater and test re-test reliability

Kappa is a statistic that is used to measure agreement beyond that expected by chance, and thus is a measure of "true agreement". It indicates the proportion of agreement beyond that expected by chance (Cohen 1960). Thus kappa is the achieved beyond-chance agreement as a proportion of the possible beyond-chance agreement (Sim and Wright, 2005). The simplest use of kappa is in the situation in which two clinicians each provide an assessment of presence or absence of a characteristic representing inter-rater reliability or when a clinician provides two assessments of the same patient in relation to the presence or absence of a characteristic, representing intra-rater (test re-test) reliability. The concern is how well the ratings agree, not with how well the ratings agree with some "gold standard" or "true" diagnosis.

The range of possible values for kappa is from -1 to 1, though it usually falls between 0 and 1. Unity represents perfect agreement, whereas zero represents agreement expected by chance. Although kappa represents the proportion of agreement greater than that expected by chance, its interpretation is not so straightforward, as there are other factors that can influence the magnitude of the coefficient or the interpretation that can be placed on a given magnitude. Among the factors that can influence the magnitude of kappa are prevalence, bias and non-independence of ratings.

Kappa can be adjusted for prevalence and bias with the resulting kappa coefficient is referred to as a PABAK (prevalence-adjusted bias-adjusted kappa). It is recommended that PABAK is presented in addition to, rather than instead of kappa. Interpretation guidelines have been proposed as standard strengths of agreement for kappa and are detail in Table 3 (Landis and Koch, 1977):

Table 3 The Kappa statistic

Kappa	Strength of agreement
≤0	Poor
0.01-0.20	Slight
0.21-0.40	Fair
0.41-0.59	Moderate
0.60-0.79	Substantial
0.81-1	Almost perfect

It has also been suggested that the interpretation of kappa could be assisted by reporting the maximum value is could attain for the set of data concerned. To calculate the maximum value of kappa (κ_{max}) the proportion of positive and negative judgements by each clinician are taken as fixed and the distribution of paired ratings is adjusted so as to represent the greatest possible agreement. In contrast to PABAK, κ_{max} serves to gauge the strength of agreement while preserving the proportion of positive ratings demonstrated by each clinician. Finally a 95% confidence interval can be constructed around kappa (Bland 2008).

We will undertake kappa (with 95% CIs), PABAK and κ_{max} to assess the inter-rater reliability for agreement of risk status overall (at risk/not at risk). To further ensure the reliability of any findings we will also examine the extent of agreement for individual PURPOSE T items.

In order to assess the test-retest reliability of PURPOSE T, the same approach of using kappa statistics and their variants PABAK and κ_{max} will be employed, except that, rather than two independent raters assessing the risk status of the patient, it will be the same rater carrying out the assessment. In order to preserve the independence of the two assessments, the two assessments will need to be far enough apart in time for the rater not to remember their original assessment (we judge an appropriate time period to be at least 1 days), but also not so far apart that the patient's condition will have altered (we judge an appropriate time period to be no more than 3-7 days).

9.3 Acceptability and data quality

Acceptability will be determined by data quality; assessed by completeness of item-level data (percent of missing data for items) and completeness of confirmation of risk status (percent of people for whom it is possible to assess risk).

9.4 Convergent validity

Convergent validity assesses the degree to which constructs (or scores on a measure) expected to be related are, in fact, related. The degree to which assessment of 'at risk' and 'not at risk' are related to risk assessment status as assessed using the Braden (Braden and Bergstrom 1987) and Waterlow (Waterlow 1985) risk assessment scales will be determined.

A Spearman Rank correlation coefficient will be calculated between PURPOSE T and Braden and Waterlow risk status. In addition, where there are corresponding items between PURPOSE T and Braden and/or Waterlow (e.g. mobility), correlations will be performed to determine how closely PURPOSE T items are related to other risk screening items. For exploratory purposes, the following hypotheses will be proposed as guides to the magnitude of correlations, as opposed to pass/fail benchmarks (high correlation $r > 0.7$; moderate correlation $r = 0.3 - 0.7$; low correlation < 0.3) (Burnand, 1990; Cohen 1960). Moderate to high correlations ($r = > 0.3$) are predicted.

9.5 Known groups validity

Known-group comparisons are used to evaluate the clinical utility of instruments or assessment tools. This method assesses the extent to which the overall assessment or items are able to discriminate between subgroups of patients known to differ in terms of clinical presentations (Kerlinger, 1973).

A chi-square test for independence (used to compare the frequencies of cases found in the various categories of one variable across the different categories of another variable) will be used to determine whether type of hospital patient (e.g. elective vs. acute) is related to risk group (e.g. at-risk vs. not at-risk).We anticipate that there will be a significantly lower proportion of elective surgical patients assessed as 'not at risk', compared to acute patients.

12.2 Ethical considerations

This study will include elderly and highly dependent patients considered as vulnerable. Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with

high levels of co-morbidity including acute and chronic illness. A large proportion of patients suffering from pressure ulcers/at risk of pressure ulcers have receptive or comprehension or language difficulties. They may also have general cognitive impairment affecting their understanding and/or dementia. To ensure that the study population is representative of the clinical population assessed in the course of usual care, recruitment procedures will facilitate consultee agreement. This is important because the nature of a pressure ulcer risk assessment includes history taking and also clinical examination, both of which are impacted when patients have cognitive impairment or language difficulties. In order to assess the reliability and validity of the PURPOSE T as the basis for use in clinical practice, it is important that the study population is a representative patient population.

The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and the use of local staff including experienced clinical nurses, that is, members of the local TVT to assess patients. In line with good clinical research practice, if a patient is clearly at risk or has an existing pressure ulcer and this is not reported in the patients' healthcare notes, then it will be documented in the patients' healthcare notes and reported to the ward/community nurse responsible for the patients care.

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000. Informed written consent/witnessed verbal consent/consultee agreement will be obtained prior to involvement into the study. The right of a patient to refuse participation without giving reasons will be respected. The patient will remain free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment. If a participant withdraws consent from further study participation their data will remain on file and will be included in the final study analysis.

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Appendix 1: Confidential DRAFT preliminary PURPOSE T

[NB: Data for the preliminary PURPOSE T was collected however the scale is omitted due to copyright. The final PURPOSE T can be obtained from URL:http://ctru.leeds.ac.uk/purpose].

Appendix 2: Reliability and Validity Tests and Criteria

Test Property	Definition/Test	Criteria (Traditional)
Data Quality Acceptability/Data completeness	The extent to which PURPOSE T items are completed and used to allocate a risk category; quality of data is assessed by data completeness for each element of the PURPOSE T and a risk category.	-% item level data missing -% of risk categories allocated -% of items missing where a risk category has been allocated
Inter-rater reliability **Test Re-Test Reliability**	Inter-rater reliability assesses the extent to which the PURPOSE T results obtained by two or more raters agree for the same population. Test re-test reliability assesses the stability of the PURPOSE T over a period of time in which the patient's condition is not expected to change.	- The kappa statistic is a measure of true agreement and indicates the proportion of agreement beyond that expected by chance, that is the achieved beyond-chance agreement as a proportion of the possible beyond-chance agreement.
Content Validity	The extent to which a scale measures what it intends to measure.	-Qualitative evidence from the PU risk factor systematic review and PU-MDS and PURPOSE T consensus study that items in the scale are representative of the construct being measured.
Convergent Validity (Between Scale analysis – analyses against external criteria) **Known group differences**	Evidence that PURPOSE T constructs are correlated with other measures of the same or similar constructs; assessed on the basis of correlations between the measure and other similar measures (Braden Scale and Waterlow Score). The ability of PURPOSE T risk categories to differentiate known groups; assessed by	-Correlations are expected to vary according to the degree of similarity between the constructs being measured by each instrument. Specific hypotheses are formulated and predictions tested on the basis of correlations.

	comparing PURPOSE T risk categories for subgroups who are expected to differ on the construct being measured (significant differences between known group or difference of expected magnitude) (e.g. elective/acute patients).	

Appendix 3: Braden Score

[NB: Data for the Braden scale was collected however the scale is omitted due to copyright. The Braden scale can be obtained from URL: http://bradenscale.com/].

Appendix 4: Waterlow scale

[NB: Data for the Waterlow scale was collected however the scale is omitted due to copyright. The Waterlow scale can be obtained from URL: http://www.judy-waterlow.co.uk/index.htm].

Appendix 32 Pressure Ulcer Risk Assessment Framework field test 1 participant information sheet

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PURPOSE

Pressure UlceR Programme Of ReSEarch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

PATIENT INFORMATION SHEET

A large-print version of this sheet is available on request.

You have been invited to take part in a research study. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with your relatives or carers if you wish. Ask us if anything is unclear, or if you would like more information. Part 1 tells you the purpose of this study and what taking part involves. Part 2 gives you more detailed information about the study. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study is part of a larger study which is trying to find a better way of identifying patients who are at risk of developing pressure ulcers (bed sores) and those who already have pressure ulcers. A group of experts and patients have worked together to work out a list of questions to ask about you and this study is to check whether we can use this list to give reliable and consistent answers. We hope that the answers to these questions will give a good indication of whether you are at risk of a pressure ulcer or not, or if you have a pressure ulcer.

Why have I been chosen?

This study is looking for people like you who are in hospital or under the care of community nursing services. Hospital patients and patients within the community will be asked to take part. The study includes people with different levels of walking and movement ability. This includes people who are able to move easily, as well as people who have difficulty moving or are unable to move. It will also include some people who already have a pressure ulcer.

Do I have to take part?

No, you do not have to take part. Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide. If you are interested we will describe the study to you and go through this Information Sheet. If you agree to take part you will be asked to sign the Consent Form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this Information Sheet and of the signed Consent Form to keep. If you do not wish to take part this will not affect the care that you are currently receiving. If you decide to take part you are free to change your mind and withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive.

What if I would like to take part but I have trouble with or am unable to write to fill in the Consent Form?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, a family member, or member of your healthcare team. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

What will happen to me if I take part?

If you agree to take part in the study, two nurses will undertake an assessment that will involve asking you some questions relating to your health and refer to relevant sections of your nursing and medical records. Both nurses will also look at your skin in the areas which are exposed to pressure. This includes having a quick check of your elbows, heels, and bottom, which are the areas that are most at risk of getting a pressure ulcer. The nurses will also look at your pressure ulcer if you have one. A nurse will come and repeat the assessment a few days later at a time convenient to you. The questions and skin check will take about 20 minutes and will take place in your own home, or on the hospital ward at a time convenient for you.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time for taking part. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. However, we hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with your healthcare practitioner (e.g. Nurse or Doctor) or other healthcare professional who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. In the unlikely event that you think you have been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from your healthcare practitioner or PALs (Patient Advice and Liaison Services).

Will my taking part be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. No names or details that would identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Involvement of your General Practitioner (GP) / Other Healthcare Practitioner

Your GP will be informed that you are participating in this study. If you are under the care of a Hospital consultant (inpatients only), they will also be informed of your participation.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point during or following completion of the study without giving a reason. A decision to withdraw at any time will not affect the standard of care you receive, nor will it affect your relationship with the medical and nursing team who are looking after you. Should you choose to withdraw, then your existing data (until withdrawal) will remain on file and will be included in the final study analysis unless you specifically withdraw consent for this.

Will my taking part in this study be kept confidential?

If you decide to participate in the study, the clinical information collected about you during the course of the study will be anonymised and kept strictly confidential. We will record your date of birth and initials on all study forms. If you agree to the second assessment the study nurse will record your NHS ID, hospital number (hospital patients only) and address and telephone number (community patients only). This will be held only by the study nurse who will destroy this information immediately following your second assessment. A copy of the Consent Form you sign, which will include your name, will be sent to the Clinical Trials Research Unit. They do not put your name on computer. They simply check that the consent form has been signed and dated properly and will securely file the form.

All information will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. The study team have a duty of confidentiality to you and will do their very best to meet this duty. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible to members of the research team. No names or details that would identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds, which is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee in order to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds West Research Ethics Committee (reference 12/YH/022).

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified in any report or publication. If you would like to obtain a copy of the published results, please ask your local contact person (see contact details below). We hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

Further information and contact details

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org. If you want further information about the study, now or in the future, please contact (*insert name*) below.

Your contact telephone numbers: (*to include local collaborator*)……
……...

Appendix 33 Pressure Ulcer Risk Assessment Framework field test 1 participant consent form

Patient Study Number:	Patient Initials:
Patient DOB:	Site ID:
Principal Investigator:	Version:

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PATIENT CONSENT FORM

Where witnessed consent is required please use the Witnessed Consent Form

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

	Patient initial after each question
1. I confirm that I have read and understand the information sheet dated 23.05.2012 (version 2) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that if I withdraw from the above study, the data already collected from me will be used in analysing the results of the study unless I specifically withdraw consent for this.	.....
4. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust and the University of Leeds, where it is relevant to my study participation. I give permission for these individuals to have access to my records.	.....
5. I consent to the storage including paper and electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the	.....

study report or other publication. This information will be confidentially destroyed at the end of the study.

6. I understand that information and results arising from this study may be used to develop new research. .....

7. I understand that a copy of this consent form will be passed to the Clinical Trials Research Unit, University of Leeds. .....

8. I understand that my GP and hospital consultant (where applicable) will be notified of my participation in this study. .....

9. I agree to take part in the study. .....

_____	_____	_____
Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____	_____	_____
Name of Person taking consent	Date	Signature

1 copy for patient, 1 for patient records, 1 for CTRU; original stored in Investigator Site File

Appendix 34 Pressure Ulcer Risk Assessment Framework field test 1 witnessed consent form

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WITNESSED CONSENT FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

Witness initial after each question on behalf of patient

1. I confirm that I have read and understand the information sheet dated 23.05.2012 (version 2) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily. .....

2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. .....

3. I understand that if I withdraw from the above study, the data already collected from me will be used in analysing the results of the study unless I specifically withdraw consent for this. .....

4. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust and the University of Leeds, where it is relevant to my study participation. I give permission for these individuals to have access to my records. .....

5. I consent to the storage including paper and electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. This information will be confidentially destroyed at the end of the study. .....

6. I understand that information and results arising from this study may be used to .....

develop new research.

7. I understand that a copy of this consent form will be passed to the Clinical Trials Research Unit, University of Leeds. .....

8. I understand that my GP and hospital consultant (where applicable) will be notified of my participation in this study. .....

9. I agree to take part in the study. .....

_____

Name of Patient

Witness statement

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Witness Date Signature

Research person taking Consent

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Person taking consent Date Signature

(1 copy for patient; 1 for patient records; 1 copy to CTRU; original stored in Investigator Site File)

Appendix 35 Pressure Ulcer Risk Assessment Framework field test 1 consultee information sheet

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PURPOSE

Pressure **U**lce**R** **P**rogramme **O**f Re**SE**arch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

CONSULTEE INFORMATION SHEET

A large-print version of this sheet is available on request.

As the relative, carer, or friend of the patient I would like you to consider their participation in a research study. As he/she is unable to tell me whether they would be willing to take part themselves, I am asking you, as someone who has a close personal relationship with the patient, to consider this invitation on their behalf and respond as you think they would respond. It is important that you should consider their past or present wishes and feelings regarding research of this nature. You may have personal views on participation in this particular research project but I am asking you to advise on their views.

Before you decide whether he/she should take part we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with anyone else you wish to, for example relative, friend, nurse or doctor. Ask us if anything is unclear, or if you would like more information. Part 1 tells you the purpose of this study and what taking part involves. Part 2 gives you more detailed information about the study. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study is part of a larger study which is trying to find a better way of identifying patients who are at risk of developing pressure ulcers (bed sores) and those who already have pressure ulcers. A group of experts and patients have worked together to work out a list of questions to ask about patients and this study is to check whether we can use this list to give reliable and consistent answers. We hope that the answers to these questions will give a good indication

of whether people are at risk of developing a pressure ulcer or not, or if they have a pressure ulcer.

Why has the patient been chosen?

This study is looking for patients' who are in hospital or under the care of community nursing services. Hospital patients and patients within the community will be asked to take part. The study includes people with different levels of walking and movement ability. This includes people who are able to move easily, as well as people who have difficulty moving or are unable to move. It will also include some people who already have a pressure ulcer.

Does the patient have to take part?

No, they do not have to take part. Taking part in this study is entirely voluntary and there is no obligation to take part – it is up to you to decide whether or not you feel it is appropriate for them to take part. If you are interested we will describe the study to you and go through this Information Sheet. If you agree for the patient to take part you will be asked to sign a Consultee Declaration Form to show that you have been consulted about the patient participating in the study and have agreed it is appropriate for them to take part. You will be given a copy of this Information Sheet and of the signed Consultee Declaration Form to keep. If you do not feel it is appropriate for the patient to take part this will not affect the care that they are currently receiving.

If you agree for the patient to take part you are free to change your mind and withdraw them from the study at any time, without giving a reason. This would not affect the standard of care they receive.

If you do not feel able to advise on the patient's views you may suggest someone else who has a close relationship with them or ask me to nominate a consultee, such as a doctor or nurse not involved in this study who knows the patient. If a nominated consultee is approached they will probably discuss the patient's wishes with you before they give advice.

What will happen to the patient if I agree they can take part?

If you agree to the patient taking part in the study, two nurses will undertake an assessment that will involve referring to relevant sections of the patient's nursing and medical records

and asking the patient some questions (if applicable) relating to their health. Both nurses will also look at the patient's skin in the areas which are exposed to pressure. This includes having a quick check of your elbows, heels, and bottom, which are the areas that are most at risk of getting a pressure ulcer. The nurses will also look at their pressure ulcer if they have one. With your agreement, one nurse will come and repeat the assessment a few days later at a time convenient to the patient. The questions and skin check will take about 20 minutes and will take place in the patient's own home, or on the hospital ward they are on, at a time convenient for them.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to the patient in taking part in this study. However, they are being asked to give some of their time for taking part. The patient's care and treatment will remain the same whether or not they take part in the study.

What are the possible benefits of taking part?

There will be no direct benefit to the patient as a result of participating in this study. However, we hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with the patient's healthcare practitioner (e.g. Nurse or Doctor) or other healthcare professional who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. In the unlikely event that you think the patient has been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from the patient's healthcare practitioner, or PALs (Patient Advice and Liaison Services).

Will taking part be kept confidential?

Yes. All information which would be collected about the patient during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about the patient will be handled in confidence. No names or details that would

identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Involvement of the patient's General Practitioner (GP) / Other Healthcare Practitioner

The patient's GP will be informed that they are participating in this study. If the patient is under the care of a Hospital consultant (inpatients only), they will also be informed of the patient's participation.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering agreeing to the patient participating, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want the patient to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind about the patient participating in the study at any point during or following completion of the study without giving a reason. A decision to withdraw at any time will not affect the standard of care the patient receives, nor will it affect their relationship with the medical and nursing team who are looking after them. Should you choose to withdraw the patient, then their existing data (until withdrawal) will remain on file and will be included in the final study analysis unless you specifically withdraw consent for this.

Will taking part in this study be kept confidential?

If you decide the patient can participate in the study, the clinical information collected about them during the course of the study will be anonymised and kept strictly confidential. We will record their date of birth and initials on all study forms. If you agree to the second assessment the study nurse will record their NHS ID, hospital number (hospital patients only) and address and telephone number (community patients only). This will be held only by the study nurse who will destroy this information immediately following their second assessment. A copy of the Consultee Declaration Form you sign, which will include your name and the patient's name, will be sent to the Clinical Trials Research Unit. They do not put your names on computer. They simply check that the Consultee Declaration Form has been signed and dated properly and will securely file the form.

All information will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. The study team have a duty of confidentiality to the patient and will do their very best to meet this duty. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible to members of the research team. No names or details that would identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds, which is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee in order to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds West Research Ethics Committee (reference 12/YH/022).

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified in any report or publication. If you would like to obtain a copy of the published results, please ask your local contact person (see contact details below). We hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

Further information and contact details

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled ‘Understanding Clinical Trials’. Contact UKCRC: Tel:

0207 670 5452; website www.ukcrc.org. If you want any further information about the study, now or in the future, please contact (insert name here) below.

Your contact telephone numbers: (*to include local collaborator*)…….

……

……..

Appendix 36 Pressure Ulcer Risk Assessment Framework field test 1 consultee declaration

Patient Study Number:	Patient Initials:
Patient DOB:	Site ID:
Principal Investigator:	Version:

[Delete this line, then print on Trust headed paper]

CONSULTEE DECLARATION FORM

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

	Consultee initial after each question
1. I confirm that I have been consulted about the patient's participation in the above study and have read and understand the information sheet dated 23.05.2012(version 2) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that the patient's participation is voluntary and that I am free to withdraw them from the study at any time without their medical care or legal rights being affected.	.....
3. I understand that if I withdraw the patient from the above study, the data already collected from them will be used in analysing the results of the study unless I specifically withdraw consent for this.	.....
4. I understand that relevant sections of the patient's healthcare records and data collected during the study may be looked at by individuals from the NHS Trust and the University of Leeds, where it is relevant to their study participation.	.....

5. I understand there will be storage including paper and electronic, of the patient's personal information for the purposes of this study. I understand that any information that could identify them will be kept confidential and that no personal information that could identify them will be included in the study report or other publication. This information will be confidentially destroyed at the end of the study. .....

6. I understand that information and results arising from this study may be used to develop new research. .....

7. I understand that a copy of this Consultee Declaration Form will be passed to the Clinical Trials Research Unit, University of Leeds. .....

8. I understand that the patient's GP and hospital consultant (where applicable) will be notified of the patient's participation in this study. .....

9. In my opinion the patient would have no objection in taking part in this study .....

_____

Name of Patient

_____ _____ _____

Name of Consultee Date Signature

Relationship to patient: _____

I have given written information and a verbal explanation to the consultee named above who has freely given their Declaration for the patient to participate.

_____ _____ _____

Name of Person Taking Consent Date Signature

1 copy for consultee, 1 for patient records, 1 for CTRU; original stored in Investigator Site File

Appendix 37 PURPOSE-T user manual

PURAF Field Test 1

Pressure Ulcer Risk Primary or Secondary Evaluation (PURPOSE T) User Notes

Summary of PURPOSE T

PURPOSE T (Pressure Ulcer Risk Primary or Secondary Evaluation Tool) is a pressure ulcer risk assessment framework (PURAF) intended to identify adults at risk of pressure ulcer development and makes a distinction between primary prevention (applicable to those at risk of pressure ulcer development) and secondary prevention (applicable to those who already have a pressure ulcer). It has been developed for use in adult populations in hospital and community settings by qualified nursing staff.

NB: PURPOSE T is not intended to assess the risk of pressure from external devices such as naso-gastric tubes and catheters etc.

The development of PURPOSE T incorporated a systematic review of pressure ulcer risk factors and a consensus study involving international experts in the pressure ulcer field (including review of pressure ulcer evidence): this allowed the numerous risk factors associated with pressure ulcer development to be carefully considered and only the most important risk factors to be included in PURPOSE T. Furthermore the use of colour within the tool allows us to identify the presence of key and less influential pressure ulcer risk factors. PURPOSE T was also pre-tested with practicing nurses allowing ambiguous or confusing elements to be identified and clarified in Field test version of PURPOSE T.

PURPOSE T does not utilise a score as other tools do - it encourages nurses to consider the profile of a patients' risk (PU risk factors present) to identify whether they are 'not currently at risk', 'at risk', or have an existing pressure ulcer and allocate them to the appropriate care pathway.

PURPOSE T has 3 steps including:

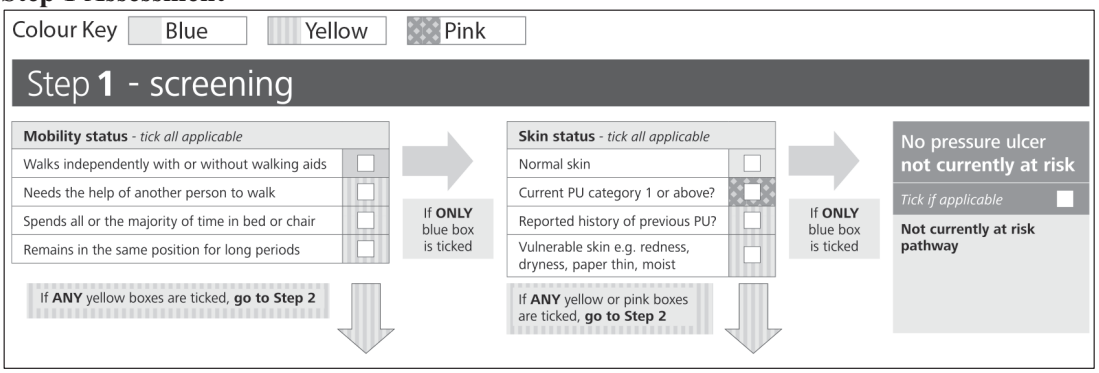
- Step 1 – Screening: complete for all patients
- Step 2 - Full Assessment: complete for those potentially at risk as determined by step
- Step 3 – Assessment Decision: to be undertaken for all patients who have undergone step 2

1. Step 1 – Screening: Complete for all patients

Step 1 comprises of two possible sections to complete:

- Mobility Status
- Skin status

Step 1 Assessment

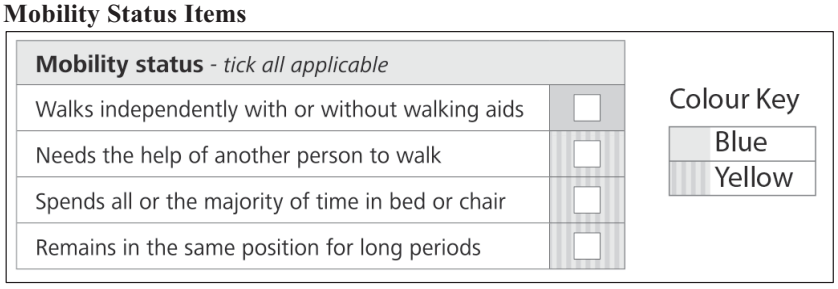


1.1 Mobility Status

This section examines mobility status items that have been developed to assess varying levels of mobility. Mobility is a key pressure ulcer risk factor, which is why it is included in the first step of the assessment.

It is important that you consider and tick **all** the item boxes that **apply** to your patient: a patient may walk independently but remain in the same position for long periods and /or spend the majority of time in bed or chair.

Mobility Status Items



'Walks independently' means they don't need assistance from another person, and 'walking aid' could be a walking stick, walking frame or even furniture. The second item 'help of another person' could involve physical assistance or verbal prompting. The latter 2 items require an element of judgement by the nurse in terms of whether the patient's length of time in one position is considered normal.

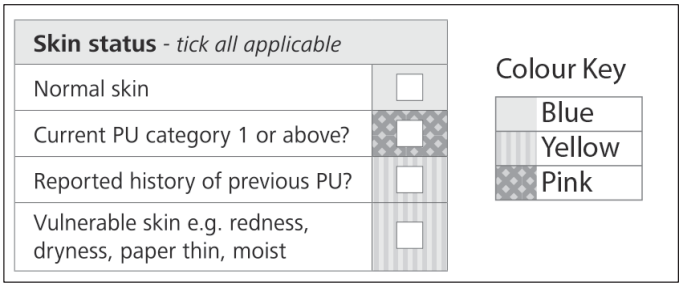
1.2 Mobility Decision Boxes

The decision boxes and colour coding will help you decide if you need to go to step 2 of the assessment straight away or if you need to complete the Step 1 skin status items: if you have ticked any yellow boxes you should progress to Step 2 without completing the Step 1 skin status items. If you have **only** ticked the blue box you should complete the Step1 skin status items.

1.3 Skin Status

This section examines skin status items which have been developed in recognition of the importance of skin status in the assessment of pressure ulcer risk. The items give a range of possibilities of pressure area skin status as commonly encountered in clinical practice.

Skin Status Items



It is important that you tick all of the boxes that apply to your patient as they may have more than one, for example a patient may have a reported history of previous pressure ulcer **and** skin vulnerability.

The item 'normal skin', requires judgement since there is no clear definition of what constitutes normal skin. It would certainly include the absence of skin vulnerability or pressure ulcers: nurses should use their clinical judgement to determine if a patient's skin is normal. The 'vulnerability' skin item gives examples of redness, dryness, paper thin and moist: these describe the visual appearance of vulnerable skin but this is not exhaustive list and you may also consider other factors. See section 2.3 for further notes on skin vulnerability and skin redness.

The nurse will need to make a judgement about the approach required to complete this section (i.e. history taking/ clinical records/ full skin inspection), while recognising that the most accurate way to assess skin status is to visually examine the skin: this may be influenced by the context of care and level of patient dependency. Any patients with a skin status problem (vulnerable, current or previous PU) will progress to Step 2 of the assessment (incorporating full visual skin inspection).

1.4 The Skin Status Decision Boxes

The decision boxes and colour coding will help you decide if you need to go to Step 2 of the assessment, or if the patient is not currently at risk.

If you have ticked any yellow or pink boxes you should progress to Step 2 of the assessment. If you have only ticked the blue box then the patient is not currently at risk and you should indicate this by ticking the 'not currently at risk' box and end the assessment without progressing to Step 2.

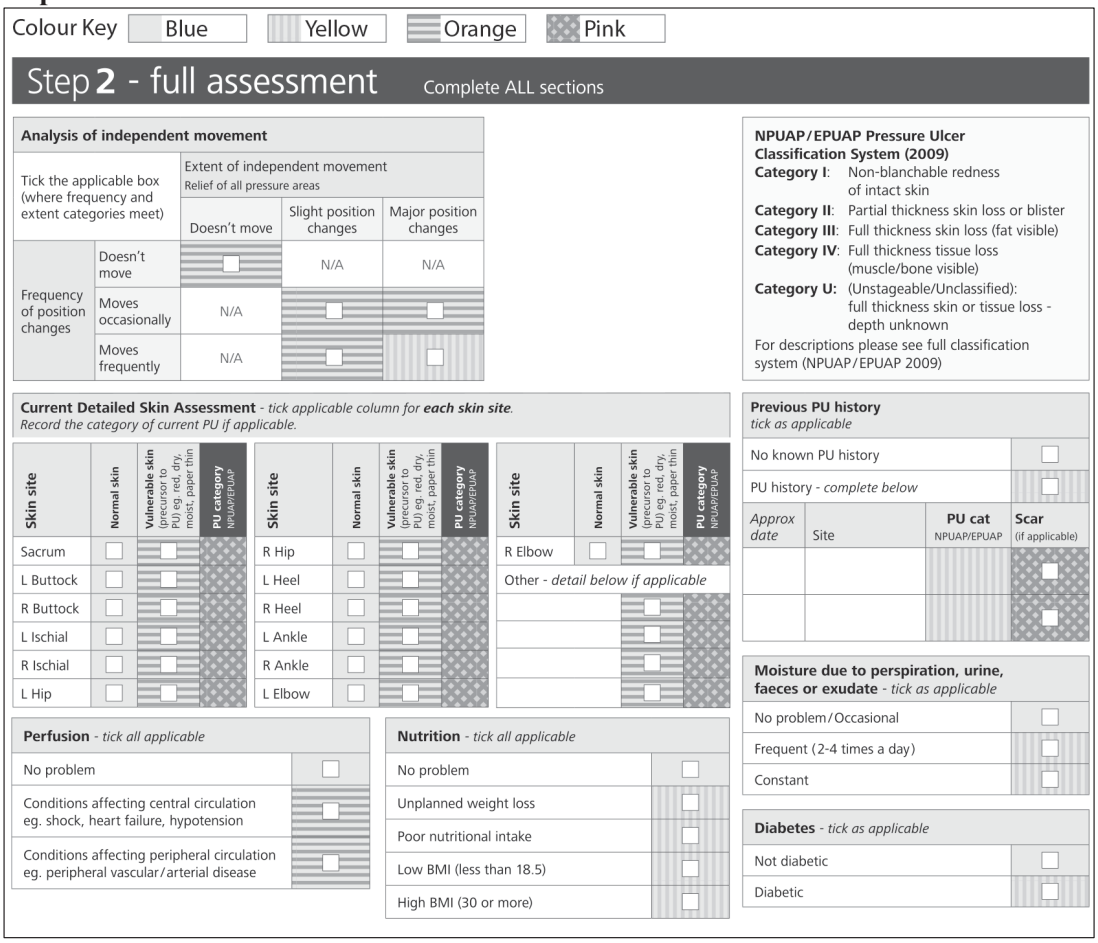
2. Step 2 - Full Assessment: Complete for those potentially at risk as determined by step 1

Step 2 consists of 8 sections which must be fully completed. The sections comprise:

- Analysis of independent movement
- Sensory perception and response

- Current detailed skin assessment
- Previous pressure ulcer history
- Perfusion
- Nutrition
- Moisture
- Diabetes

Step 2 – Full Assessment



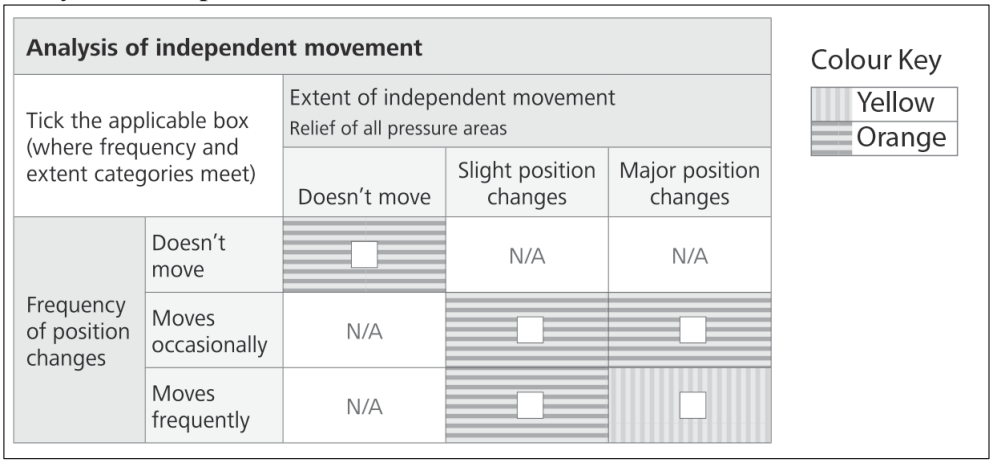
Each section will give a range of possibilities as you would encounter in clinical practice. It is important that if the patient does not have a problem with a particular risk factor that this is indicated by ticking the 'no problem' item showing the assessment has been undertaken. If you follow the flow of the sections from top to bottom and left to right you are less likely to miss any sections out, though some nurses have found it more practical to complete the visual skin inspection at the end of the assessment.

2.1 Analysis of Independent Movement

This section was developed to capture information about the patients' independent movement. 'Independent movement' relates to movement that is undertaken by the patient

without the assistance of another person, i.e. it does not relate to the movement encountered when nurses changes the patients' position or turns the patient.

Analysis of Independent Movement Item



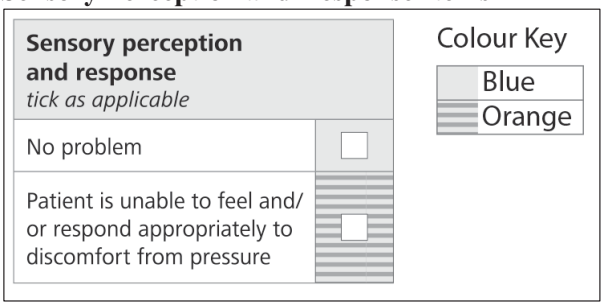
A matrix is used to bring the frequency (i.e. how often) and extent (i.e. amount) of movement together and each component has a range of options for you to consider in light of patients movement pattern. When completing the frequency element the nurse must consider what would be considered normal frequency of movement and use her clinical judgement to inform which category the patient falls into.
The 3 options relating to the extent of movement include 'the patient doesn't move', 'minor position changes' and 'major position changes'. Major position changes could include the patient turning over in bed or standing up resulting in complete pressure relief. Minor position changes could include the patient shifting their position a little when in the bed or chair which may result in some but not complete pressure relief. The patient doesn't move item relates to no pressure relief of pressure areas.

To complete the section the nurse must consider both frequency and extent of independent movement in the matrix and tick the box where the two elements meet.

2.2 Sensory Perception and Response

This section relates to sensory perception and response and comprises just 2 items. It is a tick **as** applicable section and only **one** item applies, i.e. does the patient have a problem with sensory perception and response or not.

Sensory Perception and Response Items



In your assessment you need to consider if the patient is unable to feel and/or respond appropriately to discomfort from pressure. This item recognises that patients will vary in terms of whether they can do both i.e. some patients will not be able feel discomfort from pressure and so will not respond, while others may be able to feel but not respond appropriately. Either of these scenarios indicates there is a problem with sensory perception and could lead to reduced movement and pressure relief. Factors that *may* (though not always) influence the patients' ability to feel and respond appropriately to discomfort from pressure, comprise underlying medical conditions or treatments such as MS, CVA, head injury, spinal injury, neuropathy, dementia, depression, epidural, anaesthetics and opiates. When undertaking the assessment the nurse must consider whether the presence of such factors affects the patients' sensory perception.

2.3 Current Detailed Skin Assessment

Requires a visual skin inspection and assessment of skin sites listed in the table: these include the most common pressure area skin sites though patients sometimes develop pressure ulcers in other areas and there is space for 'other' skin sites if required. This should be completed for **all** skin sites shown in the table.

Current Detailed Skin Assessment Items

Colour Key: Blue | Orange | Pink

Current Detailed Skin Assessment - *tick applicable column for **each skin site**.*
Record the category of current PU if applicable.

Skin site	Normal skin	Vulnerable skin (precursor to PU) eg. red, dry, moist, paper thin	PU category NPUAP/EPUAP
Sacrum	☐	☐	
L Buttock	☐	☐	
R Buttock	☐	☐	
L Ischial	☐	☐	
R Ischial	☐	☐	
L Hip	☐	☐	

Skin site	Normal skin	Vulnerable skin (precursor to PU) eg. red, dry, moist, paper thin	PU category NPUAP/EPUAP
R Hip	☐	☐	
L Heel	☐	☐	
R Heel	☐	☐	
L Ankle	☐	☐	
R Ankle	☐	☐	
L Elbow	☐	☐	

Skin site	Normal skin	Vulnerable skin (precursor to PU) eg. red, dry, moist, paper thin	PU category NPUAP/EPUAP
R Elbow	☐	☐	
Other - *detail below if applicable*			
		☐	
		☐	
		☐	
		☐	

Clinical judgement based on information from a holistic patient assessment should be used while undertaking the skin assessment. Each skin site should be inspected to identify normal skin, vulnerable skin (e.g. persistent redness, dry, moist, paper thin) or pressure ulcer present (also see section 1.3). When considering skin redness in relation to vulnerability, the nurse should consider if the redness is a normal transient response. The nurse must also consider the holistic patient assessment along with other elements of the purpose T assessment when making a decision about skin, e.g. if a patient is fully mobile but has been sat out and has some blanching redness this could be viewed as a normal response and not as skin vulnerability. However if a patient is immobile and the redness is persistent or intense it might be considered vulnerable.

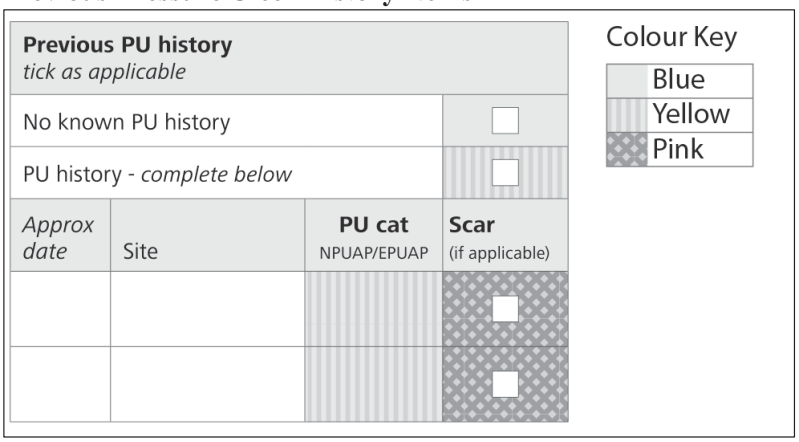
The nurse should only choose one option (normal skin, vulnerable skin or PU category) for each skin site by ticking the appropriate box. The category of any existing pressure ulcer is recorded in the pink column. The abbreviated NPUAP/EPUAP Pressure Ulcer Classification

System (2009) is listed to help you and the full version of this will be available in the study documentation.

2.4 Previous Pressure Ulcer History

The first 2 items relate to whether the patient has a reported history of a pressure ulcer and is a tick **as** applicable section and only **one** item applies, i.e. the patient either has a reported history of pressure ulcer or they don't. Some patients may not know and the patients' clinical record could provide a good source of information.

Previous Pressure Ulcer History Items



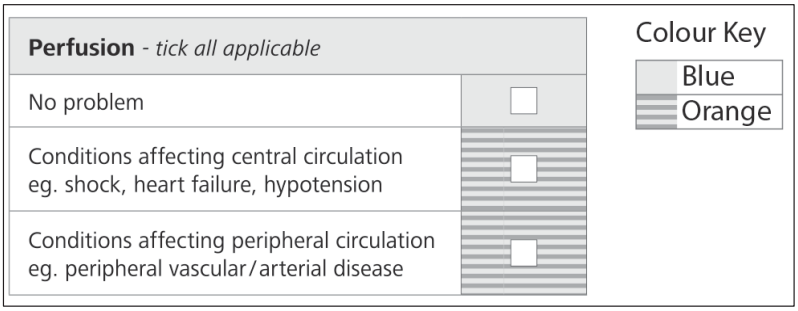
If the patient has a reported history of pressure ulcer development the approximate date, site and PU category should be recorded. The nurse should also indicate if a scar is present which could be ascertained when undertaking the current detailed skin assessment. This is important as scarring results in ongoing skin vulnerability to pressure.

2.5 Perfusion

The perfusion section includes 'no perfusion problems' and 2 items relating to conditions that affect the central circulation (shock, heart failure or hypotension) and conditions that affect peripheral circulation (peripheral vascular/arterial disease). These give some examples of conditions affecting perfusion, but this is not exhaustive list and you may also consider other factors such as poor capillary refill.

If the patient doesn't have any perfusion problems then the nurse should tick 'no problem'. If the patient does have perfusion problems the nurse should tick the **all** applicable items as some patients' may have both central and peripheral circulatory problems.

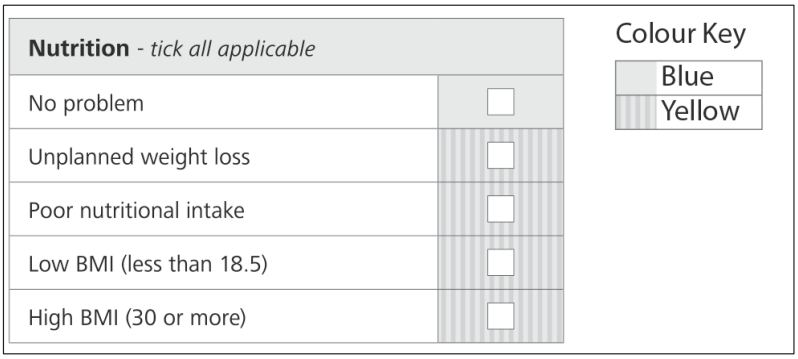
Perfusion Items



2.6 Nutrition

The nutrition items have been developed to capture patients with the varying nutrition problems as you would encounter in clinical practice. It is important that you consider all the items and tick **all** the item boxes that **apply** to your patient as there may be more than one applicable item. However, if your patient has no problems with nutrition you will only tick the applicable box.

Nutrition Items



The 4 items indicating there is a problem with nutrition comprise 'unplanned weight loss', 'poor nutritional intake', 'low BMI' and high 'BMI'. 'Unplanned weight loss' relates to weight loss that isn't sought by the patient, i.e. they haven't been trying to lose weight and may have lost it due to illness. 'Poor nutritional intake' may be relevant to patients with poor appetite who are not eating well. It may also be applicable for those are nil by mouth and obtaining no other form of nutritional support. Low BMI is less than 18.5 and high BMI is 30 or more.

2.7 Moisture

The moisture section comprises of 3 items and relates to moisture due to perspiration, urine, faeces or exudates. This is a tick **as** applicable section and only **one** item applies. The first item relates to patients' without a moisture problem or with occasional moisture which does not impact on the patients' risk of pressure ulcer development. The other items relate to the frequency of moisture with some guidance of these parameters i.e. 'frequent (2-4 times a day)' and 'constant' meaning all of the time.

Moisture Items

Moisture due to perspiration, urine, faeces or exudate - *tick as applicable*	
No problem/Occasional	☐
Frequent (2-4 times a day)	☐
Constant	☐

Colour Key: Blue; Yellow

2.8 Diabetes

This item relates to the presence of diabetes and gives 2 options. This is a tick **as** applicable section and only **one** item applies.

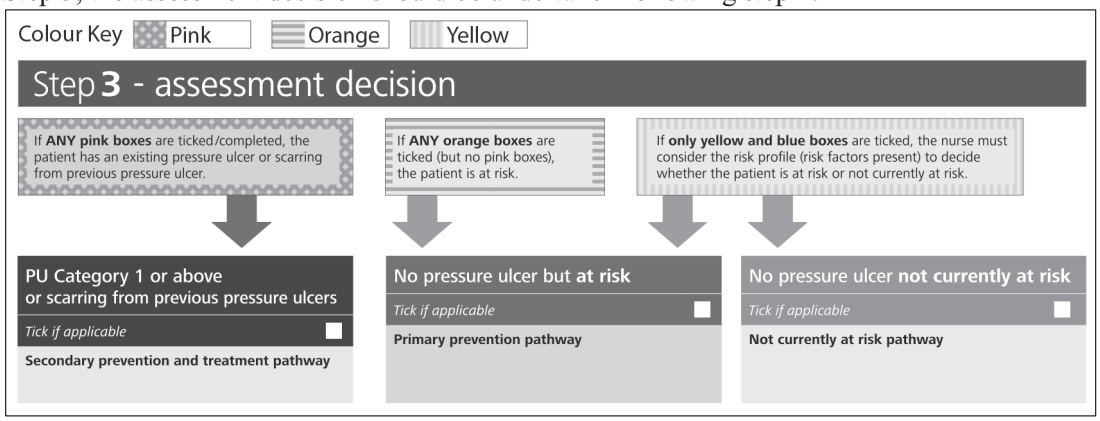
Diabetes Items

Diabetes - *tick as applicable*	
Not diabetic	☐
Diabetic	☐

Colour Key: Blue; Yellow

3. Step 3 – Assessment Decision

Step 3, the assessment decision should be undertaken following step 2.



Each item in Step 2 is highlighted by a blue, yellow, orange or pink box. These colours represent the importance of the risk factors as indicated by the level of scientific or epidemiological evidence and/or the results of the consensus study:

- Pink box items indicate the patient has an existing pressure ulcer or scarring from a previous pressure ulcer
- Orange box items indicate the presence of a key pressure ulcer risk factor
- Yellow box items indicate the presence of less influential pressure ulcer risk factors (but still important in considering the overall risk profile of a patient and in the delivery of appropriate preventative care)
- Blue box items indicate the absence of a risk factor.

When completing step 3 the nurse must carefully review the step 2 assessment to decide whether the patient should be allocated to the secondary prevention and treatment pathway, primary prevention pathway or the not currently at risk pathway.
This is facilitated by decision boxes in the PURPOSE T which indicate:

- If any pink boxes are ticked it indicates that the patient has an existing pressure ulcer or scarring from a previous pressure ulcer. The patient should be allocated to the secondary prevention and treatment pathway indicated by ticking the red box in the pathway.
- If any orange boxes (but no pink boxes) are ticked the patient does not have a pressure ulcer but is at risk of pressure ulcer development and should be allocated to the primary prevention pathway indicated by ticking the orange box in the pathway.
- If only yellow or blue boxes are ticked the nurse must consider the risk profile of the patient and use clinical judgement to determine whether the patient is ‘at risk’ or ‘not currently at risk’. The nurse should consider the number of yellow boxes ticked and the patients’ individual circumstance, for example a patient may only have the presence of unplanned weight loss but may be terminally ill and nearing the end of life where the general trajectory of dependence will increase and the nurse may therefore consider the patient to be ‘at risk’ or a young diabetic patient may have undergone acute surgery but be recovering well where the general trajectory is increasing independence so the nurse may consider the patient to be ‘not currently at risk’, but would want to review this if the patients’ condition changed. Patients with a number of yellow boxes ticked are more likely to be considered ‘at risk’.

Appendix 38 Pressure Ulcer Quality of Life qualitative study reduced format protocol

NB: This study protocol (version 3, dated 25 Jun 2008) is in a reduced format including only the study aims and methods. Sections pertaining to study background have been removed as they are included as a chapter section.

2. Study objectives

Ethics approval is sought to undertake Phase 1 development. The aim of this study is to undertake in-depth qualitative interviews with a sample of patients with PUs. The information obtained will be used to develop a conceptual framework of HRQL in PUs. This will complete the first phase of the PU-QOL measure development process.

The study objectives are:

1. To identify outcomes and HRQL issues which are relevant and important to patients with grade 1, superficial and severe PUs
2. To identify whether PROs and HRQL issues for patients with grade 1, superficial, and severe PUs are the same in relation to the impact of interventions.
3. To gain insight into the relative PU burden and what it is like to live with a PU

2.1. Study design

Development of a conceptual framework

In phase 1 of the health-outcome measure development process, the conceptual framework will be developed by utilising three sources; literature, patients, and experts in the field. A systematic review of qualitative and quantitative literature has been undertaken and from this, patient-reported themes associated with PU interventions and general issues associated with having a PU will be summarised and grouped into relevant HRQL domains. This will produce an exhaustive list (working framework) of relevant PROs that cover all HRQL domain(s) associated with PU occurrence, symptoms, and interventions. The working framework will be used for the development of an interview schedule for the qualitative interviews. Expert group review will be sought through all stages of the conceptual framework, interview schedule development, and data analysis stages.

Qualitative interviews

Each participant will be interviewed using an in-depth qualitative interview method following an interview schedule, in order to assess the impact of PUs and PU interventions on HRQL.

Up to 24 patients will be recruited from various hospitals around the UK. Each patient will be interviewed once and interviews will last approximately 1 hour. The interview will be discontinued at any time upon the patient's wishes. Interviews will consist of various probing questions to get the patient to reflect and to speak openly about their experience of having a PU. The patients will also be asked to comment and assess the importance of the HRQOL domains identified from the literature review. All interviews will be recorded.

The interviews will be conducted, recorded, and analysed by the primary researcher. The data will then be reviewed by the multidisciplinary expert group and discussed until a consensus view is achieved. This final process will produce a conceptual framework.

2.2. Inclusion/exclusion criteria

Patients with grade 1 (at-risk), superficial, and severe ulcers, from vascular, orthopaedic, medical, or care of the elderly wards, as well as patients in the community under the care of tissue viability nurse (TVN) specialists and consultants, and TVN teams, will be eligible to take part in the study.

Eligible patients will be included in the study if they fulfil the following criteria:

- understand and speak fluent English AND
- aged more than 18 years of age AND
- with current PU of any grade (1-4) (Table 1) OR
- had a PU grade 2-4 healed within the last 3 months AND
- able to share their experience in a thoughtful and reflective way AND
- able to give their written informed consent to take part

2.3. Recruitment & consent procedures

Patients will be purposively sampled (15-24 patients) ensuring balanced representation of patients in grade 1, superficial ulcer (grade 2) and severe ulcer (grade 3/4) categories. Consecutive patients will be identified from each PU category and approached to participate.

Recruitment will continue on a rolling basis until a minimum of five and maximum of eight patients from each PU group are recruited from the participating sites, and interviews undertaken. A sample size of up to 24 patients will allow for any initial changes to the interview schedule should they be required following the first few interviews.

Table 1 EPUAP pressure ulcer classification (EPUAP, Pressure ulcer treatment guidelines, 1999)

Grade 1	Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade 2	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.
Grade 3	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to but not through underlying fascia.
Grade 4	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.

TVNs at participating hospital and community services will identify potential patients. Those who meet the eligibility criteria will be approached, informed about the study, and provided with; 1) a project information sheet that includes details about the rationale, design, and personal implications of the study, and 2) an 'agree to be contacted by the researcher' form either to be contacted by telephone (PCT version) or visited at the ward (in-patient version).

Following information provision, patients will have as much time as they need to complete the "agree to researcher contact" form, which will be either faxed or posted back to the CTRU. The TVN, the researcher, and the research supervisor will be available to answer any questions that patients might have about the study. After receiving a signed agreement to be contacted form from the patient, the researcher will telephone the patient to arrange a time for the interview. The researcher will provide information about the study and interview process and will answer any questions before gaining verbal consent and arranging an interview at a mutually convenient time. For in-patients who cannot be contacted by telephone and who are expected to be in the hospital during the interview, with the patient's permission, the TVN will liaise with the researcher and patient to arrange a mutually convenient time for the researcher to see the patient on the ward to discuss the study further.

The researcher will interview patients in their own home, in the out-patient clinic, or in-patient ward, as determined by the patient's circumstances and preferences at the time of the interview. It is anticipated that a similar number of community and hospitalised patients will be interviewed. Before the interview, each participant will be given a further verbal explanation of the study by the researcher, informed that the interview will be recorded but that all identifiable information will remain anonymous, reminded that they can withdraw from the study at any time without it affecting their care, and then invited formally to participate. They will be given an opportunity to ask any questions and then if they agree to take part, the participant will be asked to sign the consent form. For any patients who may have difficulty in writing but who fully comprehend, a tape recording will be taken of the verbal agreement. All participants will be sent a thank you letter after the interview. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time, again, without giving reasons and without prejudicing any further treatment.

2.4. Data collection

Patients will be interviewed by the researcher using the patient interview schedule and guide. Details regarding the PU (i.e. PU grade, location, duration) and treatment will be requested verbally from the treating nurse. These in-depth qualitative interviews will be undertaken to establish the relative importance of HRQL domains and identify any omitted HRQL themes that are important to patients. Therefore, patients will be asked questions to get them to think about important HRQL issues and themes, comment on their subjective importance, and asked to reflect on their experience of the interventions they have received and what it is like or has been like to live with a PU.

2.5. Data analysis

Interviews will be recorded and transcribed verbatim as soon as possible following the interview. Preliminary analysis will be carried out after the first three patients have been interviewed to assess whether the interview schedules' HRQL domains compare with the emerging themes, and to identify any gaps in information. The expert group will be consulted and if deemed necessary the HRQL domains will be developed and changed as data collection progresses. Theoretical thematic analysis will be used to analyse and report

themes from the data by the researcher. Upon completion of the data analysis, a provisional report will be sent to the expert group to provide clarification and to ensure the research remains participative.

The working framework and information gathered from the qualitative interviews will formulate a conceptual framework which will be used to generate items for the PUQ-OL instrument. The following information will be sought from the interview:

- how does having a PU impact on life from the perspective of the sufferer
- what are all the HRQL issues important to PU patients and do patients find some HRQL issues more important than others
- how do PU interventions impact on patient HRQL
- what do patients feel are important intervention outcomes
- gain an understanding of the way patients define small, medium and large differences
- how important is it to patients to have HRQL issues addressed as part of their healthcare; do they think that this should be incorporated into PU management

3. Confidentiality

Any information which would allow individual participants, healthcare professionals, or wards to be identified will not be released. All the participating hospitals, community services, and the CTRU at the University of Leeds will comply with all aspects of the Data Protection Act 1998. All participants will be assigned a project number on recruitment, and confidentiality and anonymity will be maintained throughout the duration of the project and in the dissemination of results.

4. Ethical considerations

This study will recruit patients with PUs and therefore will include elderly and highly dependent patients considered as vulnerable. Clinically, older patients are treated in the same way as younger patients and it is therefore important to ensure that the study is representative of the clinical population. The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and include a thought out consent process, the use of one-to-one semi-structured interviews, and the use of experienced researchers able to provide a flexible and supportive interview environment.

This project will be conducted in accordance with the Declaration of Helsinki in its latest form. The study will be submitted to and approved by a Research Ethics Committee (REC) prior to identifying eligible patients. The CTRU will provide the REC with a copy of the final protocol, patient information sheets, consent forms, and interview schedule and guide.

Appendix 39 Pressure Ulcer Quality of Life qualitative study patient information leaflet and consent form

[Delete this line then print on Trust headed paper]

INFORMATION SHEET

PURPOSE

A patient-reported outcome measure of health-related quality of life for pressure ulcer patients (PU-QOL): Qualitative patient interviews

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse if you wish. Ask us if there is anything that is not clear or if you would like more information.

(Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Part 1

What is the purpose of the study?

At present, very few studies have been conducted to inform us about what it is like for a person to live with a pressure ulcer. Pressure ulcers, also called a bed sore or pressure sore, have many causes and although the aim is to prevent them, a small number of people still go on to develop them. This project is designed to provide us with important information about the experienced suffering of patients with pressure ulcers and the impact pressure ulcer treatments have on patients' quality of life. This information will be obtained in order to improve patient healthcare and patient health-related quality of life.

In other disease areas, quality of life questionnaires exist and patients may often be asked to fill in quality of life questionnaires as part of their routine hospital care or clinic appointment.

While healthcare professionals and researchers in other disease areas are becoming more familiar with these questionnaires, quality of life questionnaires are rarely used with pressure ulcer patients to assess the impact of the pressure ulcer or their treatments on patients' quality of life. This study forms part of a larger project aiming to develop and evaluate a self-report measure of quality of life for use with patients suffering from pressure ulcers. The questionnaire will be used to inform healthcare professionals about the perceived benefit of PU treatments from the perspective of the patient and the effect it has on their quality of life. This is the first phase of the questionnaire development process involving interviews with patients like yourself, to determine which quality of life related issues are of most importance to patients.

Why have I been invited?

We are interested in talking to people who have experience of having a pressure ulcer. Any person from *(Trust name)* who has a pressure ulcer ranging from a small red area to a more severe ulcer will be asked to participate.

Do I have to take part?

You are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part we will then ask you to sign a consent form to show you have agreed to take part. You will be given a copy of this information sheet and of the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What will happen to me if I take part?

You will be contacted to arrange a suitable interview date and time. The researcher (Claudia Gorecki) will then meet with you to go through the interview process before the discussion begins. The discussion should last around 1 hour and will take place in the ward where you are admitted at *(hospital name*). The discussion will be tape recorded. The tape recording will be used only by researchers involved in the project to write notes on the discussion and will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed.

During the interview you will be asked a few questions about your current life circumstances and asked to describe and provide information about your experience of your pressure ulcer and the treatments that you received as part of your care. We also would like to ask for permission to ask your nurse details about your pressure ulcer such as whether it is a red area or blister or much more severe; how long you have had it, and details about the treatments that you have received such as the type of dressing applied. The information will be confidential between you, the team looking after you and the researcher.

Expenses and payments

We anticipate that there will be no extra expenses for you as a result of taking part in this study, as interviews will be conducted while you are an in-patient in the hospital at a convenient time for you.

What are the possible disadvantages and risks of taking part?

The study requires approximately one hour of your time. You will be asked to think about and discuss your personal experience of having a pressure ulcer and how the pressure ulcer and treatments have impacted on your life. There is a possibility that you may find this distressing. The interview can be stopped at any point if you feel you do not want to continue. If necessary, a referral can be made to your nurse or other healthcare professionals if you are distressed by the content of the discussion.

What are the possible benefits of taking part?

There are no direct benefits to you taking part. We hope that the information we get from the interviews will help to identify all the important issues that patients with pressure ulcers have to deal with and identify the perceived benefits of treatments from the perspective of the patient. This information will then be used to formulate questions which will be put together to form a quality of life questionnaire for healthcare professionals to use in addressing quality of life impacts in patients with pressure ulcers and to provide them with a better understanding of how pressure ulcers and their treatments impact on a patients quality of life from a patient's perspective.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified

during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first. The details are included in Part 2.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You are free to change your mind at any point up to, during or following the interview. You will not be able to be identified in the study results but if you wish to withdraw any data already collected prior to publication of the results then arrangements can be made for the interview tape to be destroyed and your discussion excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Caldicott principles and the Data Protection Act 1998. Claudia Gorecki and her supervision team have a duty of confidentiality to you as a research participant and we will do their very best to meet this duty. Claudia Gorecki will store the interview tapes in a locked cabinet. Tapes will be identified by study number only and any references to names will be removed during transcription. Any identifiable data will only be accessed by the researchers. The tape recordings will be disposed of securely once data analysis is completed.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study.

What will happen to the results of the research study?

Participants will not be identified in any report/publication. The study results will be used to construct items on a questionnaire and published in a scientific journal.

Who is organising and sponsoring the research?

This project is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. The researchers and nurses are not being paid for inclusion of patients in this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by *(name of REC)* Research Ethics Committee.

Further information and contact details

Thank you for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Claudia Gorecki on 0113 3437632 or the study supervisor, Dr Jane Nixon on 0113 3431488 or speak to your tissue viability nurse who provided you with this information sheet.

Development of a Patient-Reported Outcome measure of HRQOL for Pressure Ulcer Patients (PU-QOL): Qualitative patient interview consent form

PURPOSE

Name of researcher: Claudia Gorecki
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9NG

Telephone: 0113 3437632

Please initial the boxes:

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that the above named researcher may ask my nurse additional information about my pressure ulcer history and relevant treatment. I give permission for the researcher to verbally obtain this information. ☐
4. I agree that my interview will be tape recorded and typed out. ☐
5. I understand that my interview will be coded so that only the above named researcher will be able to link my interview with my personal details. ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Claudia Gorecki	_____	_____
Name of Person taking consent	Date	Signature

One copy for patient; one copy for researcher

Appendix 40 Pressure Ulcer Quality of Life qualitative study agree to researcher contact form

[Delete this line then print on Trust headed paper- given with study information]

PURPOSE

AGREEMENT TO RESEARCHER CONTACT- (16th July 2007, Version 1.0)

Name of researcher: Claudia Gorecki
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9NG
Ph: 0113 3437632

Name of consultant/nurse: _____

Contact number: _____

Development of a patient-reported outcome measure of HRQL for pressure ulcer patients (PU-QOL): Qualitative patient interviews

Please initial the boxes:

- I have read the information sheet and kept a copy. ☐
- I am happy to discuss the study further in a visit from the above named researcher. ☐

Please complete the following details in the space provided:

Name: _____

Date of visit: _____

Time of visit: _____

Location (e.g. patient's room number, clinic room number, instructions on finding location):

_____

_____

Thank you for completing this form.

Please telephone Claudia Gorecki on 0113 3437632 as soon as an interview is arranged.

Appendix 41 Pressure Ulcer Quality of Life qualitative study interview schedule

Introduction to project and present study

- Thank you for volunteering and ask questions at any time.
- Background and explanation of project.
- Confirmation of agreeing to tape-record the interview.
- Obtain informed written consent.

Introduction to the Pressure Ulcer Quality of Life development project

The PU-QOL is a larger project, undertaken by a national group of researchers including myself, that is intended to develop and evaluate a questionnaire to measure quality of life in people who have a pressure ulcer. In order to develop such a questionnaire, it is important to obtain information directly from the people who have experience of the problem. To find out what impact a pressure ulcer and pressure ulcer treatments have on quality of life, I am interviewing around 24 people who have experienced a pressure ulcer to find out what quality of life issues are most important to them. From the quality of life issues already identified, I have grouped them into seven main themes. I will ask you to comment on these themes towards the end of our discussion.

Tape recording and anonymity

[Check comfortable, do they need toilet, glass of water; clarify what name to use]

[Spoken by interviewer] I would like to make a tape recording of this interview as that will help make sure that I catch everything you say. We think it is better than my taking notes. Before we start, can I just confirm that you are happy with that? Now what will happen to this tape is that I will take it back and our conversation will be typed out in full. When we do that we make sure that there is nothing in the document that could identify you, so, for example, your name or the name of the hospital or ward would be blanked out. Similarly, names of any other people that you mention will also be blanked out or changed so that both you and they can remain anonymous.

Clinical data and impact of pressure ulcers and interventions

[Opening discussion prompts]

- You have a sore area, can you tell me about it? What is it like to live with a pressure ulcer?
- The ward staff tell me that you have a sore area. What can you tell me about it?
- Can you tell me a little bit about yourself? Why are you in hospital?
- Do you know why you got the pressure sore?
- How did you know that you had a pressure sore?
- Some people experience discomfort around their sore such as an ache or discomfort when it is being dressed. Do you feel anything?
- What kind of symptoms have you experienced?

Current situation

- Where the patient is living – is this your permanent living arrangement or just short term? If short term, what is the long-term plan for living arrangements?
- Do you get any help at home with daily care from health-care professionals or family/friends? Is this related to your pressure sore?

General health

- How would you describe your general health?
- Try to think back to the time just before you developed your pressure sore. What was your life like then?
- What do you know about pressure ulcers (establish pressure ulcer history and current knowledge)?

Their pressure ulcer

- When did you notice any skin problems? Was a pressure ulcer present on admission or did you develop a pressure ulcer in hospital?
- When did it start/how long did it last (i.e. ongoing or healed)?
- Location(s); what stage did it progress to? How many did you develop?
- What were you told about the pressure ulcer? How did you feel?
- Have you seen it? If yes, what did you think about it? How did it make you feel? If no, has anyone else seen it? How have they described it to you?
- What has been the reaction of others when you told them about your pressure ulcer?
- Do you have any worries about it?

Treatments

- Have you received any treatment on that area? What about anything else to help that area? (Dressings, creams, others)? If so, which ones?
- Frequency of wound care (i.e. how often do you have dressing changes)?
- Who performs the wound care (i.e. dressing changes)?
- Can you tell me about your experience of the wound care treatments that you received (i.e. symptoms, acceptability, satisfaction)?
- Have any aspects of your life been affected by the wound care you received?
- What do you perceive have been the benefits of your treatments?
- How has your pressure sore been attended to; what sorts of things have been done? And who did this? What was it like?
- In terms of being in hospital for your pressure sore treatment, what is that like for you?

Pressure ulcer experience and impact

- What is the biggest problem that your pressure ulcer has caused you?
- How has it affected your everyday life/your relationships?
- How has your life changed since your ulcer developed? Anything else?
- What areas of your life have been most affected since you developed your pressure ulcer? In what way?
- What kinds of things are more difficult for you to do? Any other tasks?
- How does the pressure ulcer affect your ability to move?
- How does it affect you at work?
- Does the pressure ulcer have an impact on your psychological well-being?

Prompts for further information

- Is there anything else that I haven't asked you about your sore that you think that I should know?
- You have mentioned . . ., can you tell me more about what it has been like for you?
- Is there anything else that you would like to tell me about your pressure ulcer or treatments?
- Is there anything else about the sore that you think researchers and people who provide pressure sore care need to know?
- What would you like us to know about how it has affected you from your perspective?

Discussion of existing quality of life main themes

[Spoken by interviewer] Conversations with other people with pressure ulcers have identified various issues and problems associated with having a pressure ulcer. Some of these issues include:

- perceived pressure ulcer aetiology (reasons pressure ulcer developed, risks)
- impact of pressure ulcer on daily living – physical
- symptoms/consequences of the pressure ulcer
- psychological well-being
- social impact of pressure ulcer
- impact of treatments/wound care
- the nurse–patient relationship
- impact of pressure ulcer on health
- impact on others
- need for knowledge about the pressure ulcer
- need for treatment vs. effect of treatment on patient.

- From our conversation and from these themes, can you see anything that we have missed?
- Have you experienced anything else that we have not covered today?
- Is there anything else that you want to add about your experience?
- From all the things that we have talked about today, what is the single most important thing?

End of interview

[Collect clinical data]

- Nurse contact: name and telephone.
- Trust name; hospital, acute or community.
- Age or date of birth.
- Gender.
- Marital status.
- Ethnicity.

Close the discussion; thank the patient for their time and involvement; explain how their information will be used.

Appendix 42 Pressure Ulcer Quality of Life study search strategies and data sources

Search strategies for review of existing patient-reported outcome instruments used in pressure ulcers and chronic wounds

Searches of the following electronic databases were performed from inception until May 2012 using the search strategies below: MEDLINE, EMBASE, PsycINFO, CINAHL, BNI and AMED.

Pressure ulcer terms

1. decubitus.sh
2. skin ulcer.sh
3. exp decubitus ulcer
4. decubitus ulcer$.tw
5. pressure ulcer$.tw.
6. pressure damage$.tw
7. pressure sore$.tw
8. bed sore$.tw
9. skin ulcer$.tw
10. or/1-9

Chronic wound terms

1. chronic wound$.tw
2. leg ulcer$.tw
3. foot ulcer$.tw
4. venous ulcer$.tw
5. necrotic wound$.tw
6. ischaemic ulcer$.tw
7. arterial ulcer$.tw
8. fungating wound$.tw
9. diabetic ulcer$.tw
10. varicose vein$.tw
11. dehisced wound$.tw
12. pilonidal.tw
13. or/11-22
14. 10 or 23

Quality of life terms

1. (wellbeing or well being).ti,ab,tw,sh,kw
2. (hrql or hrqol or qol or hql or hqol).ti,ab,tw,sh,kw
3. exp quality of life
4. quality of living.tw
5. (health status or health state$).ti,ab,tw,sh,kw
6. (satisfaction or life satisfaction or satisfaction with life).tw
7. (attitude$ or emotion$ or feeling$ or mood$).tw
8. ((psycho$ or social) adj (adjust$ or adap$ or function$)).tw

9. (cope$ or coping).tw
10. exp emotion
11. exp psychological
12. exp adaptation, psychological
13. exp acceptance, psychological
14. symptom$.tw,ab,sh,kw
15. exp pain
16. pain.tw
17. comfort$.tw
18. acceptab$.tw
19. discomfort.tw
20. exp quality of sleep
21. sleep.tw
22. exp smell
23. smell$.tw
24. odo?r$.tw
25. exudat$.tw
26. or/25-49
27. (instrument$ or questionnaire$ or survey$ or measure$).kw,ab,ti
28. (patient outcome$ or patient reported outcome$ or PRO$).ti,ab,tw,sh,kw
29. health measurement$.ti,ab,tw,sh,kw
30. (categor$ scal$ or linear scal$ or linear analog$ scal$ or visual scal$ or magnitude estimat$).ti,ab.
31. or/51-55
32. 22 and 50
33. 24 and 55
34. 56 or 57

Refinement terms

1. historical article.pt.
2. review.pt.
3. (systematic adj review$).ti,ab,pt
4. (meta adj analysis).ti,ab
5. audit.ti,ab,pt
6. case report.tw,sh,mp,pt
7. (case adj stud$).ti,ab,pt
8. exp guidelines
9. letter.pt.
10. comment.pt.
11. editorial.pt.
12. burn$.tw
13. digital ulcer$.tw
14. buruli ulcer$.tw
15. spider bite$.tw
16. or/59-73
17. 58 not 74
18. limit 75 to humans, adult

The Cochrane Library and Web of Knowledge (WOK) databases were searched using 'PU' or 'pressure sore' and 'quality of life' topic words. To find relevant PRO measures not detected in the electronic bibliographic search, we hand searched specialist journals and relevant conference proceedings, contacted experts, searched the Patient-Reported Outcome and Quality of Life Database [PROQOLID; see www.qolid.org/ (accessed 9 March 2015)] and performed a citation search on all included studies and systematic reviews identified.

Pressure ulcer-related pain search strategy

Searches of the following electronic databases were performed from inception until April 2010 using the search strategies below: MEDLINE, EMBASE, PsycINFO, CINAHL, BNI and AMED.

Pressure ulcer terms

1. decubitus.sh
2. skin ulcer.sh
3. exp decubitus ulcer
4. decubitus ulcer$.tw
5. pressure ulcer$.tw.
6. pressure damage$.tw
7. pressure sore$.tw
8. bed sore$.tw
9. skin ulcer$.tw
10. or/1-9

Pain terms

1. exp pain
2. pain.tw,ti,ab,sh,kw
3. discomfort.tw
4. uncomfortable.tw
5. hurt$.tw
6. unpleasant.tw
7. throb$.tw
8. ach$.tw
9. or/11-18

Existing measures terms

1. ((pain) adj2 (questionnaire or measure$ or assess$ or survey or outcome or instrument$)).tw,ab,sh
2. (mcgill pain questionnaire or MPQ).tw
3. (brief pain inventory or BPI).tw
4. or/20-22

Qualitative methodology terms

1. qualitative.tw,ab,ti,pt,sh
2. finding$.tw
3. interview$.tw,ab
4. experience$.ti,ab,tw
5. descri$.tw,ab
6. or/24-28
7. 10 and 23
8. 10 and 19 and 29
9. 30 or 31

Refinement terms

1. (intensity rating scale$).tw
2. (numerical rating scale or NRS).tw
3. (verbal rating scale$ or VRS).tw
4. (visual analogue scale$ or VAS).tw
5. (facial recognition scale or FRS).tw
6. (present pain intensity or PPI).tw
7. historical article.pt.
8. review.pt.
9. (systematic adj review$).ti,ab,pt
10. (meta adj analysis).ti,ab
11. audit.ti,ab,pt
12. exp guidelines
13. letter.pt.
14. comment.pt.
15. editorial.pt.
16. leg ulcer.mp
17. varicose vein$.mp
18. pilonidal.tw
19. digital ulcer.mp
20. skin transplant$.mp
21. burn$.mp
22. buruli ulcer.mp
23. diabetic ulcer.mp
24. stomach ulcer.mp
25. bite.tw
26. or/33-57
27. 32 not 58

The Cochrane Library and WOK databases were searched using 'PU' or 'pressure sore' and 'pain' topic words. A citation search was performed on all included studies and relevant systematic reviews.

Hand searching

The following specialist journals were hand searched:

- *Journal of Tissue Viability*, 1990–2010
- *Journal of Wound Care*, 1991–2010
- *Wounds Repair and Regeneration*, 2000–10
- EPUAP review, 1999–2010
- *International Wound Journal*, 2004–10
- *European Wound Management Association Journal*, 2001–May 2010
- *Journal of Health and Quality of Life Outcomes*, 1999–2010
- *Journal of the American Medical Association* archive collection of 'Quality of Life', 1998–2010.

The following conference proceedings were hand searched:

- European Conference on Advances in Wound Management, 1991–2000
- Conference of the European Wound Management Association, 2001–6
- Proceedings of the European Wound Management Association and *Journal of Wound Care*, 1997–8
- 2nd World Union of Wound Healing Societies Meeting, 2004
- *Journal of Wound Healing* 2nd Conference, 2005
- Wounds UK Conference, 2004
- EPUAP Open Meeting, 1997–2007
- European Tissue Repair Society, Focus Meeting, 2000–5
- Conference of the International Society of Quality of Life Research, 1997–2007

The following dissertation databases were searched from inception to April 2010:

- ProQuest Dissertations & Theses
- Networked Digital Library of Theses and Dissertations
- International Theses in Progress
- Theses Canada Portal
- Australian Digital Theses Program
- Index to Theses
- Russian Academy of Sciences Bibliographies.

Appendix 43 Pressure Ulcer Quality of Life study items through the development process

Domain and scales	Reduced item list field test 1 ($n = 87$) – post pre-test	Original item list pre-tested ($n = 118$)
Symptoms		
Pain and discomfort	Feeling uncomfortable	Feeling uncomfortable
	Annoying pain or discomfort	Annoying pain or discomfort
	Itchiness	Itchiness
	Tenderness	Tenderness
		Niggling
		Soreness
	A dull ache[a]	Aching
		Pins and needles
	Tingling[b]	Tingling
	Throbbing	Throbbing
		Nagging
		Shooting
	Stinging	Stinging
	Stabbing pains	Stabbing
		Electric shocks
	Red raw	Red raw
	Burning	Burning
Exudate	Weeping	Weeping
		Oozing
	Running	Running
	Sticky	Sticky
		Slimy
		Wet
	Messy	Messy
	Staining	Staining
	Causing dressing to come off	Causing dressing to come off
		Gungy
	Pus	Pus
	Bleeding	Bleeding

Domain and scales	Reduced item list field test 1 ($n = 87$) – post pre-test	Original item list pre-tested ($n = 118$)
Odour	Unpleasant smell	Unpleasant smell
	Lingering smell	Lingering smell
		Dirty smell
		Foisty smell
	Stench or stink	Stench
		Stink
		Stale smell
	Pungent smell	Pungent smell
	Sickening smell	Sickening smell
	Putrid smell	Putrid smell
Physical functioning		
Mobility and movement	Difficulty sitting up in bed	Difficulty sitting up in bed
	Difficulty adjusting yourself in bed	Difficulty adjusting yourself in bed
	Difficulty turning or moving in bed	Difficulty turning in bed
	Difficulty pushing up to a sitting position	Difficulty pushing up to a sitting position
	Difficulty sitting in one position for long periods[a]	Difficulty sitting in one position for long periods
	Difficulty standing for long periods	Difficulty standing for long periods
	Difficulty transferring (e.g. from bed to a chair or to a car)	Difficulty transferring from bed to a chair
	Feeling limited in your ability to walk	Feeling limited in your ability to walk
	Feeling limited in your ability to go up and down stairs	Feeling limited in your ability to go up and down stairs
	Feeling limited in how far you were able to walk[a]	Feeling limited in how far you were able to walk
	Feeling that your walking was slowed down	Feeling that your walking was slowed down
ADL	Being able to wash yourself in your usual way (e.g. hand wash, bath, shower)	Washing yourself in the bath or shower
	Getting dressed or undressed	Getting dressed or undressed
	Doing jobs around the house (e.g. cooking, housework, DIY)	Doing housework
	Doing gardening[a]	Doing gardening
	Doing shopping	Doing shopping
	Being able to go to the toilet	Going to the toilet
		Being able to travel or drive a car
	Doing things that you enjoy (e.g. reading a book, watching a movie, using a computer)	Doing things that you enjoy
		Getting up and about to do things that you enjoy
	Being emotionally close or affectionate with loved ones	Being intimate with loved ones
	Doing your regular daily activities (e.g. work, volunteering, religious service, clubs, university)	Doing usual work

Domain and scales	Reduced item list field test 1 ($n = 87$) – post pre-test	Original item list pre-tested ($n = 118$)
General vitality	Feeling that your appetite has reduced	Feeling that your appetite has reduced
	Feeling unwell or poorly	Feeling unwell or poorly
	Feeling that your energy levels have been reduced[c]	Feeling that your energy levels have been reduced (e.g. feeling tired, fatigued)
	Feeling tired[c]	
	Feeling fatigued[c]	
Sleep	Trouble falling asleep	Trouble falling asleep
	Interrupted sleep (e.g. restless sleep or being woken up during your sleep)	Restless sleep
	Being kept awake	Being kept awake
		Being woken up during the night
	Not getting the amount of sleep that you needed	Not getting the amount of sleep that you needed
	Having to sleep in one position (e.g. your back or side)	Having to sleep in one position
	Trouble finding a comfortable position	Trouble finding a comfortable position
Psychological well-being		
Mood	Feeling frustrated	Feeling frustrated
	Feeling fed up	Feeling fed up
	Feeling annoyed or irritated	Feeling annoyed
		Feeling irritated
		Feeling bad tempered
	Feeling angry	Feeling angry
	Feeling miserable	Feeling miserable
	Feeling down[a]	Feeling down
	Feeling depressed	Feeling depressed
Anxiety and worry		Feeling fearful
		Feeling afraid
	Feeling upset[a]	Feeling upset
	Feeling concerned or worried	Feeling concerned
		Feeling worried
	Feeling anxious	Feeling anxious
		Feeling surprised
		Feeling shocked
Self-efficacy and dependence	Feeling like a burden or nuisance on others	Feeling like a burden or nuisance on others
	Feeling like you have no control over your life because of your sore	Feeling like you have no control over your life
	Feeling physically dependent on others	Feeling physically dependent on others

Domain and scales	Reduced item list field test 1 ($n = 87$) – post pre-test	Original item list pre-tested ($n = 118$)
Appearance/ self-consciousness	Feeling helpless	Feeling helpless
		Feeling a lack of self-esteem
	Feeling self-conscious	Feeling self-conscious
	Lacking in confidence	Feeling a lack of self-confidence
	Feeling embarrassed	Feeling embarrassed
	Feeling physically unattractive	Feeling physically unattractive
		Feeling disinterested in socialising
	Feeling uneasy being close to or around other people	Feeling uneasy being close to people
		Feeling worried about how others will react to your ulcer
	Feeling a lack of understanding from those close to you	Feeling a lack of understanding from those close to you
Social functioning		
Isolation		Feeling left out
		Feeling isolated
	Feeling cut off or isolated from others	Feeling cut off
	Feeling lonely	Feeling lonely
	Feeling like you were missing out	Feeling like you were missing out
	Feeling like people avoided you or treated you differently now	Feeling like people avoided you or treated you differently now
Participation		
	Difficulty going out	Difficulty going out
		Being unable to meet up with others
	Difficulty meeting up or seeing family and/or friends	Difficulty seeing family and/or friends
	Being unable to participate in family gatherings or activities	Being unable to participate in family gatherings or activities
	Having to plan going out around ulcer care	Having to plan going out around ulcer care
		Being unable to do things spontaneously
	Having to give up on hobbies or leisure activities	Giving up on hobbies or leisure activities
	Being restricted to where you could go out	Being restricted to where you could go out
	Being restricted to how long you could stay out	Being restricted to how long you could stay out
	Being unable to get away for a holiday or take a trip at the weekend	Being unable to get away for a holiday or take a trip at the weekend
	The amount of time involved in caring for your ulcer	The amount of time involved in caring for your ulcer

DIY, do it yourself.
a Items removed following field test 1 analysis.
b Items removed following field test 2 analysis.
c Item spilt into multiple items prior to field test 2 to extend the measurement range of the scale.

Appendix 44 Pressure Ulcer Quality of Life pre-test and field test study reduced format protocol

NB: This study protocol (version 5, dated 8 Mar 2010) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to adverse events, confidentiality, archiving, statement of indemnity, study organisational structure, and publication policy are available upon request

4 AIMS AND OBJECTIVES

4.1 Study aim

The aim of this study is to develop a psychometrically rigorous, self-report patient-reported outcome (PRO) measure of health-related quality of life (HRQL) in pressure ulcer (PU) patients (PU-QOL) that is acceptable to patients, reliable, valid, and suitable for use in clinical trials, epidemiological studies and in the NHS. The perspective of persons with PUs will be central in all stages of questionnaire development and evaluation. Collaboration has been sought from members of the European Pressure Ulcer Advisory Panel (EPUAP) and from various acute and primary care NHS Trusts around the UK. Ethical approval is sought to undertake phases 2 and 3 of the development and evaluation of this measure.

5 STUDY DESIGN

5.1 Overview of project research design

This multi-centre study is designed to develop and evaluate the psychometric properties of a PU-specific HRQL instrument for patients with PUs. Guidance for developing and validating health outcome measures have been consulted to ensure high quality and standardisation for the development of the PU-QOL instrument [24-26]. The guidance recommends that collaboration and expert discussion is sought and utilised through all stages of instrument development and it proposes distinct phases for the development of a PRO measure.

The research design for the PUQ-OL instrument is based on the recommended guidance and will be developed in 3 phases: 1) conceptual framework; 2) generation of items for the PU-QOL instrument and pre-testing; and 3) PU-QOL evaluation in 2 parts, a preliminary field test 1 for item reduction and a final field test 2 for psychometric properties.

Phase 1 has been conducted. A conceptual framework has been developed by tapping into 3 sources. Firstly, a systematic review and narrative analysis of HRQL outcomes literature (i.e. symptomatic consequences such as pain, foul smell, comfort/discomfort) relevant to PU interventions and patient experiences of living with a PU has been undertaken. Secondly, in-depth qualitative interviews with a sample of PU patients, and thirdly, information obtained from the systematic review and qualitative interviews produced a conceptual framework.

Phase 2 of this project will be the development and pre-testing of the provisional PU-QOL instrument. Items will be generated from the conceptual framework and patient verbatim. The provisional instrument will then be reviewed for clarity and overlap by the project team and members of the collaborating expert group. Once expert consensus is achieved and the pre-test version of the instrument is developed, pre-testing will be undertaken by interviewing a small number of patients using cognitive interview techniques. This process will assist in clarifying any ambiguities in item wording and evaluate the appropriateness of the instruments' time-frame, question stem and response options. Based on information obtained from the cognitive interviews, the provisional PU-QOL will be revised to produce a preliminary version ready for field testing.

The evaluation of the PU-QOL instrument is phase 3 of this project. It will be undertaken in 2 parts: preliminary field test 1 (item reduction) including a mode of administration sub-study (refer to Appendix 1); and final field test 2 (psychometric properties). The preliminary field test will identify any items with poor psychometric performance for possible elimination. The final stage field test will be undertaken to evaluate the item-reduced version of the PU-QOL instrument for reliability, validity, and responsiveness. Gold standard psychometric methods [27-31] will be used to evaluate the PU-QOL to ensure rigour and scientific credibility.

6 PHASE 2: PRE-TESTING

6.1 Design for Pre-Test

Principles of Cognitive Aspects of Survey Methodology (CASM) [32] have been employed in the design of this phase. Cognitive pre-testing methods (interviews with patients) will be used to indicate how respondents interpret questions, response categories, and to prepare instructions for how to formulate their responses.

6.2 Eligibility

6.2.1 Inclusion criteria

Patients from participating acute and community NHS Trusts, with existing PUs (any grade, see Table 1), will be included in the study if they are hospital in-patients or outpatients, intermediate care patients, or community patients under the care of community care nursing services, and they fulfil the following criteria:

- aged ≥18 years **and**
- with an existing PU of any grade, location, or duration **or**
- a PU that had healed within previous 3 months **and**
- able to provide written informed consent to participate **and**
- able to read and write in English

6.2.2 Exclusion criteria

Patients will also be excluded from the study if any of the following criteria apply. They:

- have only moisture lesions
- are unconscious or confused
- have cognitive impairment
- are unable to speak, read and/or write in English
- they do not have an existing PU or one that healed within previous 3 months
- are unable to provide informed consent

Table 1 EPUAP Pressure Ulcer Classification [5]

Grade 1	Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade 2	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion or blister.
Grade 3	Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to but not through underlying fascia.
Grade 4	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.

Patients who are deemed ethically inappropriate to approach by members of the Tissue Viability Team (TVT) (see section 6.4), for example, those where death is imminent (any patient who is on or meets the criteria of the Liverpool Care Pathway for the dying) will not be approached.

6.3 Methods

The provisional questionnaire will be pre-tested with a sample of patients. We estimate that approximately 40 patients will be needed to reach saturation (no new issues arising). This process is intended to clarify ambiguities in item wording and to evaluate questionnaire length, time-frame, question stem and response options, and to address any additional queries that participants may raise. Standard one-to-one cognitive interviewing techniques will be used by the researcher Claudia Gorecki (CG), who has training and experience in conducting patient interviews, to gain a better understanding of how respondents interpret questions and whether questions are understood in the way that they are intended.

This involves the researcher (CG) asking respondents to complete the questionnaire on their own but throughout completion they will be required to flag/mark any items that they find are annoying, upsetting or intrusive, or confussing/difficult to understand. After completion of the questionnaire, de-briefing questionning will be used by CG which include the use of general and specific questions and probes to: i) clarify ambiguities and/or misunderstandings in item wording; ii) identify items judged by the respondent to be either irrelevant or relevant but not included; and iii) questions relating to time-to-complete, ease of response, and whether any questions were confusing or upsetting to patients to determine instrument acceptability. De-briefing questioning will be guided by an interviewers' manual to ensure standardisation across administration.

In addition to the cognitive interviews, we will use a computerised appraisal tool, the Questionnaire Understanding Aid (QUAID) [33], to identify problems with question comprehension, including unfamiliar technical terms, vague or imprecise relative terms, vague or ambiguous noun phrases, complex syntax, and working memory overload. Results of pre-testing will be used to revise the provisional questionnaire to produce a long version of the PU-QOL for field testing. The qualitative comments made will be recorded and

reviewed. Expert opinion will be sought and appropriate revisions and modifications to the provisional questionnaire will be made based on the patient and professional recommendations.

6.4 Recruitment and consent procedure

Patients will be purposively sampled (up to 40 patients) ensuring representation of patients from all PU categories (grades 1-4, Table 1) and treatment types. Consecutive patients will be identified from each PU category and approached to participate. Recruitment will continue on a rolling basis until a minimum of 5 patients from each PU group are recruited and interviewed. A sample size of up to 40 patients will allow for any initial changes to the interview schedule should they be required following the first few interviews and will ensure that saturation is met with no new major issues emerging.

Members of the tissue viability team (TVT) which includes the local Principal Investigator, tissue viability nurse specialists, nurse consultants, and other members of their local clinical team (i.e. tissue viability and clinical research nurses) at participating trusts will identify potential patients. A record of those identified as eligible, approached to participate, refusals, and consenting patients will be made (see section 6.4.1).

Patients that meet the eligibility criteria will be approached, informed about the study, and provided with a project information leaflet which includes details about the rationale, design, and personal implications of the study, and an 'agree to be contacted by the researcher' form to be either contacted by telephone or visited at the ward.

Following information provision, patients will have as much time as they need to complete the 'agree to researcher contact' form, which will be either faxed or posted back to the Clinical Trials Research Unit (CTRU). Members of the TVT, the researcher, and the project Chief Investigator (CI) will be available to answer any questions that patients might have about the study. After receiving a signed agreement to be contacted form from the patient, the researcher will telephone the patient to arrange a time for the interview. The researcher will provide information about the study and interview process, will answer any questions about the research, and remind the patient that participation is completely voluntary and that they are free to withdraw taking part at any time, before gaining verbal consent and arranging

an interview at a mutually convenient time. For in-patients who cannot be contacted by telephone and who are expected to be in the hospital during the interview, the TVT member will (with the patient's permission) liaise with the researcher and patient to arrange a mutually convenient time for the researcher to see the patient on the ward to discuss the study further.

The researcher (CG) will interview patients in their own home (following standard safe practice SOP), in the out-patient clinic, or in-patient ward as determined by the patient's circumstances and preferences at the time of the interview. It is anticipated that a similar number of community and hospitalised patients will be interviewed.

Before the interview, each participant will be given a further verbal explanation of the study by the researcher; informed that the interview will be recorded but that all identifiable information will remain anonymous; reminded that participation is completely voluntary and that they can withdraw from the study at any time without it affecting their care; and invited formally to participate. They will be given an opportunity to ask any questions and then if they agree to take part, the participant will be asked to sign the consent form. A copy of the consent form will be given to the patient to keep, one filed in the patients' health care record, and the original copy kept by the researcher to take back to the CTRU.

The researcher is required to utilise all possible methods to ensure that no patient feels pressurised to take part in the study. This will include emphasising that participation is entirely voluntary and that participants are free to withdraw consent at any point up to, during or following the interview. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time, again, without giving reasons and without prejudicing any further treatment.

6.4.1 Non-registration

The TVT member will complete a log of all patients screened for potential participation. Anonymised information will be collected including:

- The reason not eligible for study particpation
- Eligible but declined
- Date of birth

- Gender
- Ethnicity
- Pressure ulcer grade and location

6.5 Data collection

Participants will complete the provisional questionnaire on their own but will be asked to flag/mark any items that are annoying, upsetting or intrusive, or confusing. Following completion, the researcher, guided by a standard set of questions and probes, will seek to elicit the cognitive processes employed by the participant while completing the provisional questionnaire. Data collected will relate to feedback on participants' understanding of each question and associated response category and instructions, and to verbalise how they had gone about producing their answers, with particular emphasis on retrieval from memory and subsequent judgements and decisions [32].

Questionnaire completion and follow-up interview may take around 40-60 minutes and will be discontinued at any time if participants are unable to go on or wish to discontinue. The interviews will be conducted, recorded, and analysed by CG with supervison from experienced researchers (AEN, DL), who will undertake quality assurance.

6.5.1 Baseline data

Following questionnaire completion and specific probing, the researcher will record the following information as provided by the patient:

- Patient initials and date of birth
- Gender
- Ethnicity
- Pressure ulcer grade, location and number of pressure ulcers
- Duration of pressure ulcer
- Treatment plan (information about which treatment interventions the patient is currently receiving)
- Co-morbidity and/or speciality (i.e. spinal cord injured, trauma, vascular, care of the elderly ward)

6.6 Data analysis

Review and analysis of information collected from cognitive interviews will be conducted as soon as possible after the interview, but at minimum after every 3 interviews. This will enable any major flaws in the provisional questionnaire to be identified and revised prior to subsequent testing with the revised version. This form of multiple rounds of testing will determine whether the problem identified has indeed been rectified and no new problems introduced.

A systematic way of evaluating questionnaires will be developed to ensure that each questionnaire item was assessed systematically. An appropriate tool, the Question Appraisal System (QAS-99) [34] will be used to categorise item problems identified during the cognitive interview process. The QAS-99 consists of eight major categories that focus on question characteristics that are likely to present problems when completing and forming responses to questionnaires.

Review and analysis will involve the researcher listening to the recorded interview and making structured contemporaneous notes of specific problems identified based on the categories of the QAS-99 appraisal tool. Specifically, focus will be on identifying dominant trends (problems occurring repeatedly) across interviews, and key findings (problems that may only be identified in a single interview, but have the potential to cause serious problems). Comments made, both within and across interviews, will be aggregated so that they can be used to review the provisional questionnaire. In addition to cognitive pre-testing, expert appraisal of the provisional questionnaire will inform revisions.

7 PHASE 3: FIELD TESTING

The psychometric properties of the PU-QOL will be evaluated through two-stage field testing including a preliminary field test (item reduction) to identify items with poor psychometric properties for possible elimination and identify subscales, and a final field test (psychometric evaluation) to evaluate the reliability and validity of the item-reduced version of the PU-QOL. The overall strategy and methods for the psychometric evaluation of PU-QOL are based on the methods used to develop and validate PROs in several other areas of medicine and surgery [27,28,31,35].

7.1 Design for preliminary field test 1 (item reduction)

The purpose of the preliminary field test 1 is to produce a short (item-reduced) version of the PU-QOL from the provisional version and to undertake an initial psychometric evaluation of the item-reduced questionnaire.

An item reduction strategy developed for evaluation of PROs in other medical areas [27-31] will be used to: i) identify items on the provisional version of the PU-QOL with poor psychometric properties for possible elimination; ii) conduct a preliminary evaluation of PU-QOLs' subscales; and iii) undertake a preliminary evaluation of the acceptability, reliability and validity of the item reduced PU-QOL. Results of the item reduction analyses will be used to develop a shorter version of PU-QOL for final psychometric field testing.

In addition, to address methodological issues identified from the pre-test phase relating to patient difficulties in self–completion, a mode of administartion sub-study will be undertaken to determine the mode of administration in which the questionnaire will be developed and validated (ie both self-complete and interview-administered modes or interview-administered only) (see Appendix 1 for details of the sub-study).

There are two possible outcomes from the sub-study:

1) One questionnaire can be developed and psychometrically evaluated for use with either of the two modes of administration (i.e. self-complete and interview-administered modes) or;
2) Two mode-specific questionnaires are required.

If the analysis of the sub-study finds that one questionnaire can be developed for use with either mode of administration, all of the following sections of the protocol will apply. If the analysis finds that two mode-specific questionnaires are required, only the interview-administered sections of the subsequent protocol will apply.

7.2 Eligibility

Patients from participating acute and community NHS Trusts, with existing PUs (any grade, see Table 1), will be included in the study if they are hospital in-patients or outpatients, intermediate care patients, nursing home patients or community patients under the care of community care nursing services, and they fulfil the criteria detailed below in section 7.2.1.

Patients who took part in pre-testing will not be approached to take part in the field testing phase.

7.2.1 Inclusion criteria

- aged ≥18 years **and**
- with an existing PU of any grade, location, or duration **and**
- able to provide informed consent to participate

7.2.2 Exclusion criteria

Patients will also be excluded from the study if any of the following criteria apply. They:

- have only moisture lesions
- are unconscious or confused
- have cognitive impairment
- do not speak or understand English
- they do not have an existing PU **or**
- are unable to provide informed consent

Patients who are deemed ethically inappropriate to approach by members of the Tissue Viability Team (TVT), for example, those where death is imminent (any patient who is on or meets the criteria of the Liverpool Care Pathway for the dying) will not be approached.

7.3 Methods

An approximate sample of 150-250 PU patients will be purposively sampled ensuring representation of patients with all PU categories (grades 1-4, Table 1) and treatment types. There are no formal sample size estimation methods for evaluation of PRO measures, so the 'rule of thumb' recommendation of 5-10 patients for every item in the questionnaire has been used to estimate the sample size of 150-250 patients [24]. Consecutive patients will be identified and approached to participate. Accrual will be reviewed to ensure that there is balanced representation of patients in all PU categories. If we are validating the questionnaire for both modes of administration (i.e. self-complete and interview-administered modes) then accrual will be monitored to ensure equal numbers of patients are recruited into both mode groups. Where possible patient recruitment will be piggy-backed onto local audit and Quality Assurance (QA) activity (prevalence surveys, incidence monitoring, critical

incidence reporting) to maximise the identification of patients with PUs whilst minimising disruption and demand on the local clinical team.

7.4 Recruitment and consent procedures

Members of the TVTs at participating trusts will identify eligible patients. A record of those identified as eligible, approached to participate, refusals, consenting patients and questionnaire returns will be made (see section 7.4.1 and 7.5).

A verbal explanation of the study and Patient Information Leaflet will be provided by the TVT member or the researcher* (CG) for the patient to consider. These will include detailed information about the rationale, design and personal implications of the study. Following information provision, patients will have as much time as they need to consider participation and will be given the opportunity to discuss the study with their family and healthcare professionals before they are asked whether they would be willing to take part. The right of the patient to refuse consent without giving reasons will be respected.

Should the patient be capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member, career or friend or another member of the patient's healthcare team who is not directly involved in the research study.

**Where the researcher is involved in the recruitment and consent process, the patient will be asked to give verbal permission to be approached by the researcher*

Assenting patients will then be invited to provide informed, written consent to collect baseline assessment data and to complete the questionnaire. Formal eligibility assessment and informed consent will be undertaken by the TVT member or researcher. The patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. The original consent form will be filed within the PURPOSE Investigator Site File or designated secure location. One copy of the consent form will be given to the patient and one will be filed with the patients medical file.

7.4.1 Registration

Patients will be registered with the CTRU following informed consent and confirmation of eligibility. When eligibility has been confirmed, registration and baseline data (section 7.5.1) will be collected and a questionnaire pack containing the final provisional PU-QOL will either be provided to the patient to self-complete or be administered. Registration and baseline information and completed questionnaire packs will be collected from the patient by the attending TVT member, recognising the potential for completion bias this may incur. However, in this patient population and in order to maximise questionnaire return rates, collection of the questionnaires by the attending TVT member is considered essential.

7.4.2 Screening

The TVT member will complete a log of all patients screened for eligibility who are not registered either because they are ineligible or because they declined participation. All anonymised screening logs will be returned to the CTRU.

Anonymised information will be collected including:

- The reason not eligible for study particpation or
- Eligible but declined
- Date of Birth
- Gender
- Ethnicity
- Pressure ulcer grade and location

7.5 Data collection/assessment

Study data will be recorded by members of the TVTs or the researcher on the case record forms (CRFs) and by patients, members of the TVTs or the researcher on questionnaire booklets. Anonymised data will be returned to the CTRU.

Assessments will be undertaken as follows:

- Registration and Baseline data
- PU-QOL Questionnaire booklet

7.5.1 Registration and Baseline Data

Patients who meet the inclusion criteria and provide informed written consent (for baseline assessment and questionnaire completion) will be registered to this study. Registration and baseline information will be recorded by the TVT member or researcher including:

- Patient initials and date of birth
- Gender
- Ethnicity
- Marital status
- Education
- Presence of PU symptoms
- Pressure ulcer grade, location and number of pressure ulcers
- Duration of pressure ulcer
- Treatment plan (information about which treatment interventions the patient is currently receiving)
- Co-morbidity and/or speciality (i.e. spinal cord injured, trauma, vascular, care of the elderly ward)
- Centre code
- Name of the TVT/clinical research staff member conducting registration
- Confirmation of eligibility and written informed consent
- Braden scale

7.5.2 PU-QOL questionnaire booklet

Self-complete version

The patients will self-complete the PU-QOL questionnaire booklet, which will be provided to them by the person obtaining consent (i.e. member of the TVT or the researcher (CG)). It is anticipated that completion of the questionnaire may take up to 40 minutes.

Interview-administered version

A questionnaire pack will be administered to patients by either a member of the TVT or the researcher, following an interview manual. It is anticipated that administration of the questionnaire may take up to 40 minutes. Training in administering the questionnaire will be provided by the CTRU.

7.6 Item reduction analysis

The purpose of the item reduction analysis is to produce a psychometrically robust short version of the PU-QOL questionnaire. Standard psychometric tests and criteria for acceptability, reliability and validity will be performed to identify and retain items with strong psychometric properties and eliminate items with poor psychometric properties to produce a shorter, item-reduced version of the PU-QOL questionnaire. These analyses will also evaluate the hypothesised subscales of the questionnaire

Item reduction analysis will include item analysis and principal component factor analyses, including missing data <5%, maximum endorsement frequencies <80% (floor/ceiling effects <80%), aggregate adjacent endorsement frequencies >10%, item redundancy (inter-item correlations <0.75), internal consistency (item-total correlations <0.25), evidence of item responsiveness, and tests of scaling assumptions (item convergent/discriminant validity). A preliminary psychometric evaluation of the short, item-reduced version will be carried out using standard psychometric tests for acceptability, reliability (internal consistency), and validity (factor analysis, item convergent/discriminant validity).

In addition to standard psychometric tests, methods from modern measurement theory will be used to evaluate the psychometric properties of the PU-QOL questionnaires' scales and items [36]. This is proposed in order to strengthen methodological rigour.

8 FIELD TEST 2: PSYCHOMETRIC EVALUATION

8.1 Design for field test 2

In order to establish the PU-QOL as a valid measure of PU HRQL and to determine whether the instrument meets gold-standard criteria, scientific psychometric tests of acceptability, reliability, and validity will be performed.

A questionnaire pack will be provided to patients to self-complete or be administered to them. The pack will include the PU-QOL instrument and additonal measures selected for validation purposes (section 8.5.1). In addition, a sub-sample of the patients who complete and return the questionnaire packs at baseline will be asked to self-complete or have administered to them a second (re-test) questionnaire pack 2-7 days after the initial questionnaire completion.

8.2 Eligibility

Patients from participating acute and community trusts, with existing PUs (any grade, see Table 1), will be included in the study if they are hospital in-patients or hospital outpatient, or intermediate out-patient, nursing home patients or community patients under the care of community care nursing services, and they fulfil the criteria detailed in section 7.2.

8.3 Methods

An approximate sample of 150-250 PU patients (5-10 patients for each item on the PU-QOL instrument) will be purposively sampled ensuring representation of patients with all PU categories (grades 1-4, Table 1) and treatment types. Consecutive patients will be identified and approached to participate. Accrual will be reviewed to ensure that there is balanced representation of patients in all PU categories. If we are validating the questionnaire for both modes of administration (i.e. self-complete and interview-administered modes) then accrual will be monitored to ensure equal numbers of patients are recruited into both mode groups. Where possible, patient recruitment will be piggy-backed onto local audit and QA activity (prevalence surveys, incidence monitoring, critical incidence reporting) to maximise the identification of patients with PUs by the local clinical team.

Test-Retest

A test-retest will be undertaken with a sub-sample of participants recruited for the final field test. Consenting participants will complete a second questionnaire pack 2-7 days after the first questionnaire pack (approximately 75 patients for each mode of administration group). The length of the test-retest interval must be short enough to ensure that clinical change in the PU is unlikely to occur, but sufficiently long to ensure that respondents do not recall their responses from the first assessment. A short test-retest interval is necessary to ensure that stability per se is being evaluated, rather than clinical change in the PU during the test-retest interval, which will underestimate reliability.

8.4 Recruitment and consent procedure

Members of the TVTs at participating trusts will identify eligible patients. A record of those identified as eligible, approached to participate, refusals, consenting patients and questionnaire returns will be made (see section 7.4.1 and 7.5). The recruitment and consent methods described above in the preliminary field test will be used (section 7.4).

In addition to the information described in section 7.4, the patient information leaflet for the final field test indicates that participants can take part in 2 ways: 1) self-complete or administered questionnaire booklet at baseline, and if they agree, 2) complete a second self-complete or administered questionnaire booklet 2-7 days later. There will be an option on the consent form where participants can indicate whether they agree to take part in a second questionnaire. In addition to the original consent form being filed within the PURPOSE Investigator Site File or designated secure location, one copy for the patient, and one for the patient's medical notes, a copy of the consent form will be sent to the CTRU.

Self-complete version

If patients who self-complete a questionnaire at baseline agree, they will provide home address details so that a second questionnaire booklet can be given to them when the first booklet is collected or sent out to them with a return stamped, self-addressed envelope. Where patients are still hospital in-patients, they will complete the second questionnaire on the ward and return it to the researcher or TVT member that provided it to them.

Interview-administered version

If patients who were administered a questionnaire at baseline agree, they will provide home address details so that a second questionnaire booklet can be administered to them at a time agreed by the patient and the person administering the questionnaire (must be between 2-7 days after baseline administration). Where patients are still hospital in-patients, they will have a second questionnaire pack administered to them on the ward. The researcher or TVT member that administered the questionnaire pack will be responsible for returning completed questionnaires to CTRU.

8.5 Data collection/assessments

Study data will be recorded by members of the TVTs on the CRFs and by patients on questionnaire packs. Data will be returned to the CTRU.

Assessments will be undertaken as follows:

- Registration and Baseline
- PU-QOL Questionnaire booklet

- 2-7 day follow-up questionnaire pack (approx. 75 patients from baseline sample)

8.5.1 Registration and baseline Data

Baseline information will be recorded by the TVT member including:

- Patient initials and date of birth
- Gender
- Ethnicity
- Marital status
- Education
- Presence of PU symptoms
- Pressure ulcer grade, location and number of pressure ulcers
- Duration of pressure ulcer
- Treatment plan (information about which treatment interventions the patient is currently receiving)
- Co-morbidity and/or speciality (i.e. spinal cord injured, trauma, vascular, care of the elderly ward)
- Centre code
- Name of the TVT/clinical research staff member conducting registration
- Confirmation of eligibility and written informed consent
- Braden scale

8.5.2 PU-QOL questionnaire pack

Baseline questionnaire pack will include:

- The Provisional PU-QOL
- SF-12 (rather than SF36 to reduce respondent burden)
- Additional questionnaires selected for validation purposes (ethics will be notified about which questionnaires are selected, section 8.5.3)

Test-retest questionnaire pack will include:

- The Provisional PU-QOL
- SF-12 (rather than SF36 to reduce respondent burden)
- Additional questionnaires selected for validation purposes (ethics will be notified about which questionnaires are selected, section 8.5.3)

8.5.3 Assessment instruments

The Short Form-12 Health Survey Questionnaire

Use of the SF-36 was considered however it was decided by the project team that it was too long for use with PU patients. Instead, the SF-12 will be used to reduce respondent burden. The SF-12 is a generic instrument that assesses HRQL in eight domains of physical functioning, role-physical, body pain, general health, energy/fatigue, social functioning, role-emotional and mental health. These are the same domains as the SF-36. Even though this instrument has not been validated for use with PU patients, it has been used with other related chronic-skin wound conditions to validate their corresponding disease-specific HRQL instruments.

Additional questionnaires

Participants will complete the short version of the PU-QOL, the SF-12, and additional measures to assess construct validity (convergent, discriminant, known groups). The guiding principle in selecting the validating measures will be to include measures that will allow a comparison of PU-QOL subscales with measures of similar constructs (convergent validity) and with measures of different constructs (discriminant validity), and to compare PU-QOL scores in clinically defined known groups whose HRQL would be expected to differ. At this stage it is not possible to anticipate the subscales and item stem of the PU-QOL until it has been developed (pre-testing, section 6). As such, selection of validating measures is not possible. However, where available, short versions of measures selected for validation purposes and only measures deemed essential for validation testing will be included in the questionnaire packs. All measures will be administered in the same order. It is anticipated that completion of questionnaire packs may take up to an hour.

8.6 Psychometric evaluation analysis

Analyses will include examination of:

Item-level performance will determine missing data (<5%), maximum endorsement frequencies (<80%), and item redundancy (inter-item correlations <0.75).

Acceptability will be assessed by completeness of data (e.g. missing data for summary scores <5%) and score distributions (e.g. distribution of endorsement frequencies across response categories, skew and floor/ceiling effects for summary scores <10%).

Reliability will be assessed on the basis of internal consistency (Cronbach's alpha for summary scores ≥0.70 and item-total correlations ≥ 0.30) and test-retest reliability (correlations for summary scores ≥0.70).

Validity will include a within-scale analyses to determine whether a single entity (construct) is being measured and that items on the measure can be combined to form a summary score (Cronbach's alpha ≥0.70), and analysis against external criteria (convergent, discriminant and known groups differences validity). To evaluate convergent validity we will compare PU-QOL with the SF-12, and additional relevant measures as determined once the PU-QOL questionnaire is developed. Discriminant validity will be assessed by examining PU-QOL scores by age, gender and medical specialty. PU-QOL scores for patients by PU severity (superficial vs severe), site of PU (heel vs elsewhere), and sensitivity impaired vs. no sensitivity impaired will be compared to evaluate known group differences. Factor analysis, together with the results of other item-level analyses described in table 2, will be used to investigate hypothesised subscales.

Evaluation of subscales will be determined by factor analysis and item convergent/ discriminant validity

In addition to standard psychometric tests, modern psychometric methods will be used to strengthen methodological rigour [36].

12 ETHICAL CONSIDERATIONS

This project will recruit patients with PUs and therefore will include elderly and highly dependent patients considered as vulnerable. Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. Clinically, older patients are treated in the same way as younger patients and it is therefore important to ensure that the study is representative of the clinical population. In addition, questionnaire completion/interview requires the patient to reflect on their experience of having a PU and how interventions received have impacted on their QOL. For some people this may raise topics considered to be sensitive, embarrassing or upsetting, and possibly emotionally distressing.

The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and include a thought out consent process, the use of one-to-one

semi-structured interviews using de-briefing questioning for data collection at the development pre-testing stage to provide a caring and supportive environment in which to discuss any sensitive issues that may arise, and the use of only essential measures required for validation purposes (short version where available) to reduce respondent burden. If the patient becomes distressed during the interview or from completing the questionnaire, then the interview will be immediately stopped. It will be stressed to all patients that they are able to withdrawn from participation at any time without giving reason, and without any effect on their care. They will be referred back to their treating nurse specialist if required.

This study will be conducted in accordance with the Declaration of Helsinki in its latest form. The study will be submitted to and approved by a REC prior to identifying eligible patients. The CTRU will provide the REC with a copy of the final protocol, patient information leaflets, consent forms, and all other relevant study documentation.

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APPENDIX 1 – MODE OF ADMINISTRATION SUBSTUDY

BACKGROUND TO SUB-STUDY

Initially, the purpose of the PU-QOL study was to develop and psychometrically evaluate a HRQL questionnaire for patients with pressure ulcers as a self-complete mode of administration questionnaire. However, preliminary analysis of the pre-test data has identified problems with completion rate, posing a question about the appropriateness of a self-complete measure for patients with pressure ulcers, particularly elderly patients aged over 80 years. To address these methodological issues identified from the pre-test, we are proposing to undertake a mode of administration sub-study. The sub-study will determine the mode of administration for which the questionnaire will be developed and validated.

Aim and objectives

The purpose of the sub-study is to determine whether one questionnaire can be developed and validated for use with both modes of administration or whether two mode-specific questionnaires are required.

METHODS

Design

A mode of administration sub-study including a differential item functioning (DIF) analysis [37] will be undertaken to establish measurement equivalence across two mode of administration groups (self-complete and interview-administered modes). A DIF analysis will investigate the equivalence of the PU-QOLs' questionnaire items by comparison of these two groups.

A sample of 60-100 patients are required for the sub-study. Consecutive patients will be approached to take part. Eligible patients who provide written informed consent will be randomised to either the self-complete or interview-administered groups (see section 2.2).

We plan to develop one PU-QOL questionaire – the results of the sub-study will determine whether PU-QOL should be developed as interview-administered only OR both self-complete and interview-administered (see section 5 for more details).

Eligibility

To ensure an equivalent or representative sample in both mode of administration groups (i.e. both groups need to have the same clinical presentation to perform a differential item

functioning analysis, see section 6), the eligibility criteria has been adapted from the main study to include only patients who are able to read and write in English (i.e. patients able to self-complete a questionnaire will be randomised to both mode of administration groups).

Patients from participating acute and community NHS Trusts, with existing PUs (any grade, see Table 1), will be included in the sub-study if they are hospital in-patients or outpatients, intermediate care patients, nursing home patients or community patients under the care of community care nursing services, and they fulfil the criteria detailed below in section 2.2.1. Patients who took part in pre-testing will not be approached to take part in the sub-study.

Inclusion criteria

- aged ≥18 years **and**
- with an existing PU of any grade, location, or duration **and**
- able to provide informed consent to participate **and**
- able to read and write in English (i.e. able to self-complete a questionnaire)

Exclusion criteria

Patients will also be excluded from the study if any of the following criteria apply. They:

- have only moisture lesions
- are unconscious or confused
- have cognitive impairment
- are unable to read or write in English
- they do not have an existing PU **or**
- are unable to provide informed consent

Patients who are deemed ethically inappropriate to approach by members of the Tissue Viability Team (TVT), for example, those where death is imminent (any patient who is on or meets the criteria of the Liverpool Care Pathway for the dying) will not be approached.

Recruitment and consent

Members of the TVTs at participating trusts will identify eligible patients for the sub-study. A record of those identified as eligible, approached to participate, refusals, consenting patients and questionnaire returns will be made (see section 3.1).

A verbal explanation of the study and patient information leaflet will be provided by the TVT member or the researcher* (CG) for the patient to consider. These will include detailed information about the rationale, design and personal implications of the study. Following information provision, patients will have as much time as they need to consider participation and will be given the opportunity to discuss the study with their family and healthcare professionals before they are asked whether they would be willing to take part. The right of the patient to refuse consent without giving reasons will be respected.

Should the patient be capable of giving consent but physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member or friend of the patient or another member of the patient's healthcare team who is not directly involved in the research study.

**Where the researcher is involved in the recruitment and consent process, the patient will be asked to give verbal permission to be approached by the researcher*

Assenting patients will then be invited to provide informed, written consent to collect baseline assessment data and to complete the questionnaire. Formal eligibility assessment and informed consent will be undertaken by the TVT member or researcher. The patient will remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. The original consent form will be filed within the PURPOSE Investigator Site File or designated secure location. One copy of the consent form will be given to the patient and one will be filed with the patients medical file.

Screening and registration

The TVT member will complete a log of all patients screened for eligibility who are not randomised or registered either because they are ineligible or because they declined participation. All screening logs will be returned to the CTRU.

Anonymised information will be collected including:

- The reason not eligible for study particpation **or**
- Eligible but declined
- Date of Birth
- Gender

- Ethnicity
- Pressure ulcer grade and location

Registration and randomisation

Screened patients who are both eligible for sub-study participation and provide written informed consent will be registered and randomised to the sub-study. Informed consent for entry into the sub-study must be obtained prior to randomisation. Following confirmation of written informed consent and eligibility, registration and baseline data will be collected (see section 7.5), and patients will be randomised into the study by an authorised member of staff at the study research site.

Randomisation will be carried out by the Clinical Trials Research Unit (CTRU), at the University of Leeds, using a telephone randomisation service that will ensure allocation concealment. Randomisation will be performed using the CTRU 9.00–17.00 telephone randomisation service (9:00 to 17:00 Monday to Friday excluding public/bank holidays, the period between Christmas and New Year and all Tuesdays following a bank holiday except for Mayday).

The following information will be submitted prior to randomisation:

- Patients details including initials, gender, date of birth
- confirmation of eligibility
- confirmation of written informed consent
- date of written informed consent
- details relating to the stratification factors

Patients who fulfil the eligibility criteria, and have given written informed consent, will be randomised on a 2:1 basis to receive either self-complete or interview-administered mode of administration. The 2:1 ratio will be used to account for the likelihood of increased missing data from self-completed questionnaires; a minimum of 30 fully completed questionnaires are required for the DIF analysis. Randomisation will be stratified by: age (≤ 70, >70 years), and PU severity (superficial vs. severe PU).

Direct line for randomisation: 0113 343 xxxx

Assessments and data collection

Study data will be recorded by members of the TVTs or the researcher on the case record forms (CRFs) and by patients, members of the TVTs or the researcher on questionnaire booklets. Data will be returned to the CTRU.

Assessments will be undertaken as follows:

- Registration and Baseline data
- Randomisation
- PU-QOL Questionnaire booklet

Baseline assessment

Patients who meet the inclusion criteria and provide informed written consent (for baseline assessment and questionnaire completion) will be registered to this sub-study. Registration and baseline information will be recorded by the TVT member or researcher including:

- Patient initials and date of birth
- Gender
- Ethnicity
- Marital status
- Education
- Presence of PU symptoms
- Pressure ulcer grade, location and number of pressure ulcers
- Duration of pressure ulcer
- Treatment plan (information about which treatment interventions the patient is currently receiving)
- Co-morbidity and/or speciality (i.e. spinal cord injured, trauma, vascular, care of the elderly ward)
- Centre code
- Name of the TVT/clinical research staff member conducting registration
- Confirmation of eligibility and written informed consent
- Braden scale

PU-QOL questionnaire booklet

Self-complete version

The patients will self-complete the PU-QOL questionnaire booklet, which will be provided to them by the person obtaining consent (i.e. member of the TVT or the researcher (CG)). It is anticipated that completion of the questionnaire may take up to 40 minutes.

Interview-administered version

A questionnaire pack will be administered to patients by either a member of the TVT or the researcher following and interview manual. Training in administering the questionnaire will be provided by the CTRU. It is anticipated that administration of the questionnaire may take up to 40 minutes.

Sample size

To perform a differential item functioning (DIF) analysis, a minimum of 30 fully completed questionnaires (i.e. no missing data) are required for each mode of administration group. Consecutive patients will be randomised until a minimum of 30 fully completed questionnaires are collected from each mode of administration group (30 self-completed and 30 interview-administered questionnaires). We anticipate approximately 100 patients are required for the sub-study to meet the data requirement for the DIF analysis.

DIF analysis

The purpose of the sub-study analysis is to determine whether the PU-QOL questionnaire can be used with either self-complete or interview-administered modes or whether there is the need to develop and validate two mode-specific versions of the questionnaire (i.e. a self-complete version and an interview-administered version).

The DIF analysis will determine whether scores are directly comparable between both modes of administration (i.e. whether scores from both modes of administration are similar enough to continue developing and validating one version of the questionnaire, or whether scores are divergent and there is a requirement to develop two mode-specific questionnaires).

DIF techniques match scores on questionnaires from different groups according to their total questionnaire scores and then investigate how the different groups performed on individual questionnaire items to determine whether the questionnaire items are creating problems for a

particular group [37] (i.e. specific mode of administration group). DIF is based on the assumption that test takers who have similar knowledge (based on total test scores) should perform in similar ways on individual test questions regardless of various demographics. To ensure that the DIF analysis is a valid interpretation of group differences dependent on mode of administration and not an artefact of differences within the groups; differences that could present if for example younger, healthier patients were assigned to the self-complete group and older, more frail patients were assigned to the interview-administered group, only patients who meet the inclusion criteria (section 2.2) will be included in the sub-study. This will ensure that both group's participants are matched on clinical presentation and relevant underlying ability before determining whether participants of the two groups differ in their probability for success [37].

There are 2 possible outcomes of the analysis:

1. One questionnaire can be developed and validated for use with either mode of administration or
2. Two mode-specific questionnaires are required.

The outcome of the sub-study will determine the mode of administration in which the questionnaire will be developed and validated (ie both self-complete and interview-administered modes or interview-administered only).

Appendix 45 Pressure Ulcer Quality of Life pre-test study patient information leaflet and consent form

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Participant Information Leaflet and Agree to Contact Form

PURPOSE

PUQOL Project Pre-test: patient interviews

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

The development of pressure ulcers, also called a bed sores or pressure sores, can have a major impact on patients' quality of life and well-being as well as severely compromise all areas of functioning. However, there is currently no formal way of assessing quality of life outcomes from the patients' perspective in healthcare and in research, as there is no quality of life questionnaire for use with patients with pressure ulcers.

The Pressure Ulcer Quality of Life (PUQOL) project will develop a questionnaire that will assess important quality of life outcomes in patients with pressure ulcers that will be suitable for use in NHS clinical practice and in research. Specifically, the questionnaire will provide us with important information about the experienced suffering of patients with pressure ulcers and the impact pressure ulcer treatments have on patients' quality of life. This information will be obtained in order to improve patient healthcare and patient quality of life.

This study is the second phase of the development of the questionnaire and involves interviews with patients like yourself. Patients will complete the provisional version of the questionnaire and upon completion, will be asked to answer a series of questions about the questionnaire. The provisional questionnaire will be modified based on all patients' answers and recommendations.

Why have I been invited?

You have been chosen to take part because we wish to talk to people who have experience of having a pressure ulcer. Any person who has a pressure ulcer ranging from a small red area to a more severe ulcer, from hospitals and within the community around the United Kingdom, will be asked to participate.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part we will then ask you to sign a consent form to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What will happen to me if I take part?

If you agree to take part, you will be asked to complete a questionnaire which will take approximately 20 minutes to complete. It would involve choosing an answer to a set of questions on a scale. An example of a question that you might be asked is:

> In the past week, for how many days did your pressure ulcer cause you pain or ache? (*please tick one box*)
>
> None at all ☐ between 1-3 days ☐ between 4-5 days ☐ between 6-7 days ☐

While completing the questionnaire, you will be required to mark any questionnaire items that are annoying, upsetting or intrusive, or misunderstood. After completion of the questionnaire, the interviewer, Claudia Gorecki, will ask you some questions about the items

you marked to clarify ambiguities and/or misunderstandings in the questionnaire wording. You will also be asked questions relating to the time it took to complete, ease of response options, and general questionnaire content. All people who take part are being asked the same questions. Completion of the questionnaire and the follow-up interview could possibly take up to an hour so participants who agree to take part in the study would need to be available for up to an hour. We will make sure the interview took place in as private a place as possible, either in your own home or on the ward where you are admitted, at a time convenient for you. No further involvement is required.

The discussion that you have with the interviewer about the questionnaire, with your permission, will be tape recorded and transcribed to help us analyse it. The tape recording will be used only by researchers involved in the project and it will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed. In addition to the information collected during the interview, we may need to access your medical records to obtain further information about your pressure ulcer and the treatments that you have received.

Expenses and payments

We anticipate that there will be no extra expenses for you as a result of taking part in this study, as interviews will be conducted in your own home or on the hospital ward where you are admitted at a time convenient for you.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and by completing the questionnaire, you will need to reflect on your personal experience of having a pressure ulcer and how the pressure ulcer and treatments have impacted on your life. There is a possibility that you may find this distressing. The interview can be stopped at any point if you feel you do not want to continue. If necessary, a referral can be made to your nurse or other healthcare professionals if you are distressed by the content of the questionnaire or by the discussion that will follow completion.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the information we get from the interviews will help to develop a questionnaire that covers all the important issues that people with pressure ulcers have to deal with and the perceived benefits of treatments from the perspective of the sufferer.

Will my taking part in this study be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first. Details are included in Part 2.

This completes part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point up to, during or following the interview. You will not be able to be identified in the study results but if you wish to withdraw any data already collected prior to publication of the results then arrangements can be made for the interview tape to be destroyed and your discussion excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Data Protection Act 1998.

Claudia Gorecki and her supervision team have a duty of confidentiality to you as a research participant, and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your medical records, will have your name and address removed so that you cannot be recognised from it. All information obtained is strictly confidential and will be kept in locked cupboards and will

only be accessible by members of the research team. No names or details that would identify specific people will be included in the findings from this study. Findings, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be used to modify and update the provisional questionnaire to produce a preliminary version of the questionnaire which will then be further tested for its usefulness. Information from this study will be included in a final report for the whole project and published in a scientific journal.

Who is organising and sponsoring the research?

This study is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. This study is also phase 2 of the PUQOL project that is funded by the National Institute of health Research as part of a larger pressure ulcer programme aimed to reduce the impact of PUs on patients and develop methods to capture outcomes important to patients such as quality of life.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the *(name of REC)* Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please let your district nurse or tissue viability nurse who provided you with this information leaflet know. They will complete the Agree to Researcher Contact Form at the end of this leaflet and

send it back to the researcher, Claudia Gorecki, who will phone you upon receiving the form to discuss this study further and arrange a time for the interview.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Claudia Gorecki on 0113 3437632 or the study supervisor, Dr Jane Nixon on 0113 3431488 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

[Delete this line then print on Trust headed paper- given with study information]

PATIENT AGREEMENT TO RESEARCHER CONTACT

Name of researcher: Claudia Gorecki
Clinical Trials Research Unit
University of Leeds
LS2 9PH
0113 3437632

Name of consultant/nurse: _____

Contact number: _____

PURPOSE

PUQOL Project-Preliminary test: patient interviews

Please the tick relevant box

Please initial the boxes:

- I have read the information sheet and kept a copy. ☐
- I am happy to be contacted by telephone by the above named researcher to discuss the study further ☐

OR

- I am happy for my nurse to arrange a time for me to meet with the researcher on the ward ☐

Please complete your contact details in the space provided

Patient name _____

Address _____

_____Postcode_____

Telephone Number _____Preferred contact time _____

OR

Hospital name _____ Ward _____

Date and time of visit_____

Thank you for completing this form. Please return to Claudia Gorecki at CTRU, University of Leeds, Clinical Trials Research House, 71-75 Clarendon Road, Leeds, LS2 9PH or phone 0113 343 7632

[Delete this line then print on Trust headed paper- given with study information]

PURPOSE

PUQOL Project Pre-test: patient interview consent form

Name of researcher: Claudia Gorecki
Address: Clinical Trials Research Unit, University of Leeds, Clinical Trials Research House, 71-75 Clarendon Road, Leeds, LS2 9PH; **Telephone:** 0113 3437632

	Please initial box after each question
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected.	☐
3. I understand that the above named researcher may ask my nurse additional information about my pressure ulcer history and relevant treatment. I give permission for the researcher to verbally obtain this information for the above study and any further research that may be conducted in relation to it, provided that strict confidentiality is maintained.	☐
4. I agree that my interview will be tape recorded and typed out, maintaining anonymity.	☐
5. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous.	☐
6. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication.	☐
7. I understand that a copy of this Consent Form will be sent to the CTRU	☐
8. I agree to take part in the above study.	☐

Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Name of Person taking consent	Date	Signature

(When completed, 1 for patient, 1 for patient file; 1 for CTRU)

Appendix 46 Pressure Ulcer Quality of Life pre-test study interview schedule

General introduction

Thank you for participating in this interview. Your feedback about the questionnaire will help us to develop a questionnaire that is easy to understand and simple to complete. The purpose of this interview is to get feedback from you on a quality of life questionnaire, specifically the questionnaire's layout and instructions, and help us to determine whether any of the specific questions are confusing or ambiguous and might need rewording. I would like to tape-record this interview so that I remember everything that you tell me. Do I have your permission to record the interview? As well as recording, I will be taking notes.

Introduction: think aloud method

The interview format will be what we call a 'think aloud' process. What this involves is asking you to think out loud while you read and complete the questionnaire. Now, thinking out loud may be new and unfamiliar to you, but please know that there are no right or wrong answers so feel free to say anything that you're thinking. I am only interested in knowing what is going through your mind when you read the questions and try to find the most appropriate answer to represent your experience. To explain this process to you in more detail, as you read the questionnaire and answer the questions, I would like you to tell me out loud any thoughts that go through your mind. For example, as you read the questionnaire, you might be thinking that a particular sentence is a little confusing or difficult to understand so I would want you to tell me this. You might also find that a particular question is not clear and you're not entirely sure what the question is asking you; this I would also like you to tell me. So basically any thoughts about what you are reading and thinking while completing the questionnaire. Do you have any questions? We will now start the actual interview.

- I noticed that you hesitated – can you tell me what you were thinking?
- Talk me through what you are thinking while answering the question.

Introduction: debrief probing method

As part of this interview, I'm going to ask you to complete a questionnaire about the impact of pressure ulcers on quality of life. I will leave you for a little while (approx. 10–15 minutes) so that you can complete the questionnaire on your own. Take as much time as you need to read and complete the questionnaire. While you complete the questionnaire I would like you to circle, mark or underline any words that you do not understand or any individual questions that you find to be confusing, intrusive or ambiguous; basically, mark any problems that you find with the questionnaire. Feel free to write any comments in the margins and note any questions or problems that arise while you are completing the questions. There are no right or wrong answers. I am only interested in knowing which questions may be problematic in terms of wording, understanding and so on. After you complete the questionnaire I will come back and you can tell me about how it was for you completing the questionnaire. I will also ask you some questions about what you were thinking while you completed the questions and we can discuss any questions that you circled or marked and discuss any comments that you made. Do you have any questions before we get started?

Probing questions

Content and instruction probes

- What do you think this questionnaire is about?
- What to you is '(*quality of life*)'? Determine if anything is omitted.
- Any areas of your life that your pressure ulcer affects that the questionnaire didn't ask you about?
- Did you understand the instructions? Was any part confusing or difficult to understand?

Layout probes

- What do you think about the layout of the questionnaire? *(i.e. general format, stem, items)*
- What do you think about the length of the questionnaire?

Response option probes

- How easy or hard was it to tell the difference between each response choice?
- You chose '(*a little bother*)' as your answer, what does '(*a little bother*)' mean to you?
- Would you change any questions to make them easier to understand? What would you do?

Time frame probes

- When answering the questions, did you compare now to how you were a week ago?
- When you read 'in the last week', which days did you think of? *(Which day.)*
- Would you have responded differently to this question(s) if I had asked you about your experience over the last 14 days or 30 days instead of only the last week?
- Did you think mostly about your experience on specific days or times of day, or what was typical for you over the last week? *(If specific day/times of day.)* Can you tell me more about what made you think about those specific days/times?

Item stem probes: item by item and overall (comprehension/ interpretation/recall)

- What do the words '(*difficulty with general movement*)' mean to you?
- Describe your general movement *or* describe a typical day and the activities that you might do. Did you consider all these when you answered question 1?
- Can you tell me in your own words what you think question '(1a)' is asking?
- How would you say this question in your own words?
- How easy/hard was this question to answer? How would you reword it to make it easier?
- Do you find any of the questions sensitive?
- Are the questions worded in the language that you would use?
- How did you arrive at that answer?
- For question '(*1a*)' you chose '(*response option*)' How did you get that answer?
- How well do you remember this? *(Test recall of the relevant information.)*
- How do you remember this? *(Study recall strategy.)*
- How hard was it answer? *(Determine level of difficulty/likelihood of estimation/guessing.)*
- Was this hard/easy to answer? *(Determine comprehension and overall ability to recall.)*

Patients with multiple pressure ulcers

- For patients with more than one pressure ulcer, go through each question and ask them which pressure ulcer they thought about when they answered this question.
- While completing the questions, did you think about the pressure ulcer that was most bothersome? Or did you answer thinking about overall combined affect?

Finally, what could we do, if anything, to improve this questionnaire or any specific questions when we use them in the future with other people like you?

Closing

Thank you for taking the time to complete this questionnaire and for talking with me about what it was like for you. Now that we have completed the interview, do you have any questions?

Appendix 47 Pressure Ulcer Quality of Life field test 1 patient information leaflet and consent form

[Delete this line then print on Trust headed paper]

PURPOSE

Field test 1 & sub-study participant information leaflet and consent form

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

The development of pressure ulcers, also called a bed sore or pressure sore, can have a major impact on patients' quality of life and well-being as well as severely compromise all areas of functioning. However, there is currently no formal way of assessing quality of life from the patients' perspective in healthcare and in research, as there is no quality of life questionnaire for use with patients with pressure ulcers.

The Pressure Ulcer Quality of Life (PU-QOL) project will develop a questionnaire that will assess important quality of life issues in patients with pressure ulcers that will be suitable for use in NHS clinical practice and in research. Specifically, the project questionnaire will provide us with important information about the experienced suffering of patients with pressure ulcers and the impact pressure ulcer treatments have on patients' quality of life. This information will be obtained in order to improve patient healthcare and patient quality of life.

This study is the third phase of the development of the project questionnaire and involves patients like you, either completing the project questionnaire on your own or with assistance.

This study is undertaken so that we can determine whether the project questionnaire is a useful questionnaire for assessing quality of in people with pressure ulcers.

Why have I been invited?

You have been chosen to take part because we wish to develop this questionnaire from the perspective of people who have a pressure ulcer. This will ensure that the questionnaire covers issues that are important to patients who are affected by pressure ulcers ranging from a small red area to a more severe ulcer. Participants from many hospitals and from within the community will be asked to take part.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part you will be asked to sign the consent form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, a family member, career, or member of your healthcare team not directly involved in the research. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

What will happen to me if I take part?

If you agree to take part, you will be asked to complete a questionnaire booklet either on your own in your own time or with assistance. Completing this booklet will take approximately 40 minutes. It would involve choosing an answer to a set of questions on a response scale. An example of a question that you might be asked is:

In the past week, for how many days did your pressure ulcer cause you pain or ache? (*please tick one box*)

None at all ☐ between 1-3 days ☐ between 4-5 days ☐ between 6-7 days ☐

When you have completed the questionnaire booklet, you will be expected to either hand it back to your district or tissue viability nurse, or send it back to the Clinical Trials Research Unit in the stamped, self-addressed envelope that was provided to you with this leaflet. No further involvement is required. Your anonymised, completed questionnaire booklet will be used only by researchers involved in the project and it will be stored in a locked cabinet. In some instances, we may need to access your health care records to obtain additional information about your pressure ulcer and the treatments that you have received.

Expenses and payments

We anticipate that there will be no extra expenses for you as a result of taking part in this study, as completion of the questionnaires will take place in your own home or on the hospital ward where you are admitted at a time convenient for you.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time for completing the questionnaires. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the questionnaire that we are developing will help people with pressure ulcers in the future.

Will my taking part in this study be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point up to, during or following completion of your questionnaires. You will not be able to be identified in the study results but if you wish to withdraw any questionnaire data collected prior to publication of the results then arrangements can be made for your questionnaire to be destroyed and your responses excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Data Protection Act 1998.

Claudia Gorecki and the project team have a duty of confidentiality to you as a research participant and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your health care records, will have your name and address removed so that you cannot be recognised from it. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible by members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be based on the development of the project questionnaire. Information from this study will be included in a final report for the whole project and published in a scientific journal.

Who is organising and sponsoring the research?

This study is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. This study is also phase 3 of the project that is funded by the National Institute of Health Research as part of a larger pressure ulcer programme aimed to reduce the impact of pressure ulcers on patients and develop methods to capture outcomes important to patients such as quality of life.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the North West Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please let your district nurse or tissue viability nurse who provided you with this information leaflet know. They will ask you to complete the consent form at the end of this leaflet and either provide you with the questionnaire booklet to complete on your own or assist you in completing the questionnaire booklet. Completed booklets will be sent back to the researcher, Claudia Gorecki.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Claudia Gorecki on 0113 3437632 or the study supervisor, Professor Jane Nixon on 0113 3431488 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

(Delete this line then print on headed paper)

Patient DOB: Day Month Year | Patient Study ID:

PURPOSE

PU-QOL field test 1& sub-study consent form

Name of researcher: ……

Please initial box after each question

I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

1. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected. ☐
2. I understand that sections of any of my health care notes or questionnaire data may be looked at by responsible individuals from the study office or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my information and questionnaire data. ☐
3. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐
4. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. ☐
5. I agree to take part in the above study. ☐

Name of Patient	Date	Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

Name of Person taking consent	Date	Signature

(When completed, 1 for patient, 1 for patient file; 1for local PI)

Patient DOB: Day Month Year	Patient Study ID:

[*Delete this line, then print on Trust headed paper*] PURPOSE

PU-QOL field test 1& sub-study witnessed consent form

Witness initial after each question on behalf of the patient

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected. ☐
3. I understand that sections of any of my health care notes or questionnaire data may be looked at by responsible individuals from the study office or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my information and questionnaire data. ☐
4. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐
5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. ☐
6. I understand that a copy of this Consent Form will be sent to the Clinical Trials Research Unit ☐
7. I agree to take part in the above study. ☐

_____ _____

Name of Patient *Relationship of witness to Patient*

Witness statement

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Witness *Date* *Signature*

Research person taking Consent

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Person taking Consent *Date* *Signature*

Appendix 48 Pressure Ulcer Quality of Life field test 2 patient information leaflet and consent forms

[Delete this line then print on Trust headed paper]

PURPOSE

Field test 1 & sub-study participant information leaflet and consent form

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

The development of pressure ulcers, also called a bed sore or pressure sore, can have a major impact on patients' quality of life and well-being as well as severely compromise all areas of functioning. However, there is currently no formal way of assessing quality of life from the patients' perspective in healthcare and in research, as there is no quality of life questionnaire for use with patients with pressure ulcers.

The Pressure Ulcer Quality of Life (PU-QOL) project will develop a questionnaire that will assess important quality of life issues in patients with pressure ulcers that will be suitable for use in NHS clinical practice and in research. Specifically, the project questionnaire will provide us with important information about the experienced suffering of patients with pressures and the impact pressure ulcer treatments have on patients' quality of life. This information will be obtained in order to improve patient healthcare and patient quality of life.

This study is the third phase of the development of the project questionnaire and involves patients like you, either completing the project questionnaire on your own or with assistance.

This study is undertaken so that we can determine whether the project questionnaire is a useful questionnaire for assessing quality of life in people with pressure ulcers.

Why have I been invited?

You have been chosen to take part because we wish to develop this questionnaire from the perspective of people who have a pressure ulcer. This will ensure that the questionnaire covers issues that are important to patients who are affected by pressure ulcers ranging from a small red area to a more severe ulcer. Participants from many hospitals and from within the community will be asked to take part.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part you will be asked to sign the consent form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, a family member, career, or member of your healthcare team not directly involved in the research. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

What will happen to me if I take part?

If you agree to take part, you will be asked to complete a questionnaire booklet either on your own in your own time or with assistance. Completing this booklet will take approximately 40 minutes. It would involve choosing an answer to a set of questions on a response scale. An example of a question that you might be asked is:

> In the past week, for how many days did your pressure ulcer cause you pain or ache? (*please tick one box*)
>
> None at all ☐ between 1-3 days ☐ between 4-5 days ☐ between 6-7 days ☐

When you have completed the questionnaire booklet, you will be expected to either hand it back to your district or tissue viability nurse, or send it back to the Clinical Trials Research Unit in the stamped, self-addressed envelope that was provided to you with this leaflet.

We will also ask you to complete the same questionnaire booklet 2-7 days after the first completion; however, you can opt out of this second participation if you wish. You will be asked to indicate on the consent form at the end of this information leaflet whether you would be happy to complete a second questionnaire booklet. Your anonymised, completed questionnaire booklets will be used only by researchers involved in the project and will be stored in a locked cabinet. In some instances, we may need to access your health care records to obtain additional information about your pressure ulcer and the treatments that you have received.

Expenses and payments

We anticipate that there will be no extra expenses for you as a result of taking part in this study, as completion of the questionnaires will take place in your own home or on the hospital ward where you are admitted at a time convenient for you.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time for completing the questionnaires. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the questionnaire that we are developing will help people with pressure ulcers in the future.

Will my taking part in this study be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

Taking part in this study is entirely voluntary and you are free to change your mind at any point up to, during or following completion of your questionnaires. You will not be able to be identified in the study results but if you wish to withdraw any questionnaire data collected prior to publication of the results then arrangements can be made for your questionnaire to be destroyed and your responses excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Data Protection Act 1998.

Claudia Gorecki and the project team have a duty of confidentiality to you as a research participant and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your health care records, will have your name and address removed so that you cannot be recognised from it. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible by members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be based on the development of the project questionnaire. Information from this study will be included in a final report for the whole project and published in a scientific journal.

Who is organising and sponsoring the research?

This study is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. This study is also phase 3 of the project that is funded by the National Institute of Health Research as part of a larger PU programme aimed to reduce the impact of PUs on patients and develop methods to capture outcomes important to patients such as quality of life.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the North West Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please let your district nurse or tissue viability nurse who provided you with this information leaflet know. They will ask you to complete the consent form at the end of this leaflet and either provide you with the questionnaire booklet to complete on your own or assist you in completing the questionnaire booklet. Completed booklets will be sent back to the researcher, Claudia Gorecki.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Claudia Gorecki on 0113 3437632 or the study supervisor, Professor Jane Nixon on 0113 3431488 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

Patient DOB: Day Month Year | Patient Study ID:

PURPOSE

PU-QOL field test 2 consent form

Name of researcher: .....

Please initial box after each question

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected. ☐
3. I understand that sections of any of my health care notes or questionnaire data may be looked at by responsible individuals from the study office or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my information and questionnaire data. ☐
4. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐
5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. ☐
6. I understand that a copy of this Consent Form will be sent to the Clinical Trials Research Unit ☐
7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	*Date*	*Signature*

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____	_____	_____
Name of Person taking consent	*Date*	*Signature*

I agree to take part in completing a second questionnaire booklet in 2-7 days' time after I have completed the first questionnaire booklet. ☐

If agree to complete second questionnaire booklet, please complete contact details

Address:_____

Postcode:_____ **Telephone:** _____

(Delete this line then print on headed paper)

Patient DOB: Day Month Year	Patient Study ID:

PURPOSE

Witness initial after each question on behalf of the patient

PU-QOL field test 2 witnessed consent form

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected. ☐
3. I understand that sections of any of my health care notes or questionnaire data may be looked at by responsible individuals from the study office or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my information and questionnaire data. ☐
4. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐
5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. ☐
6. I understand that a copy of this Consent Form will be sent to the Clinical Trials Research Unit ☐
7. I agree to take part in the above study. ☐

_____ _____

Name of Patient *Relationship of witness to Patient*

Witness statement

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Witness *Date* *Signature*

Research person taking Consent

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Person taking Consent *Date* *Signature*

I agree to take part in completing a second questionnaire booklet in 2-7 days' time after I have completed the first questionnaire booklet. ☐

If you agree to complete a second questionnaire booklet, please complete your contact details

Address:_____

_____

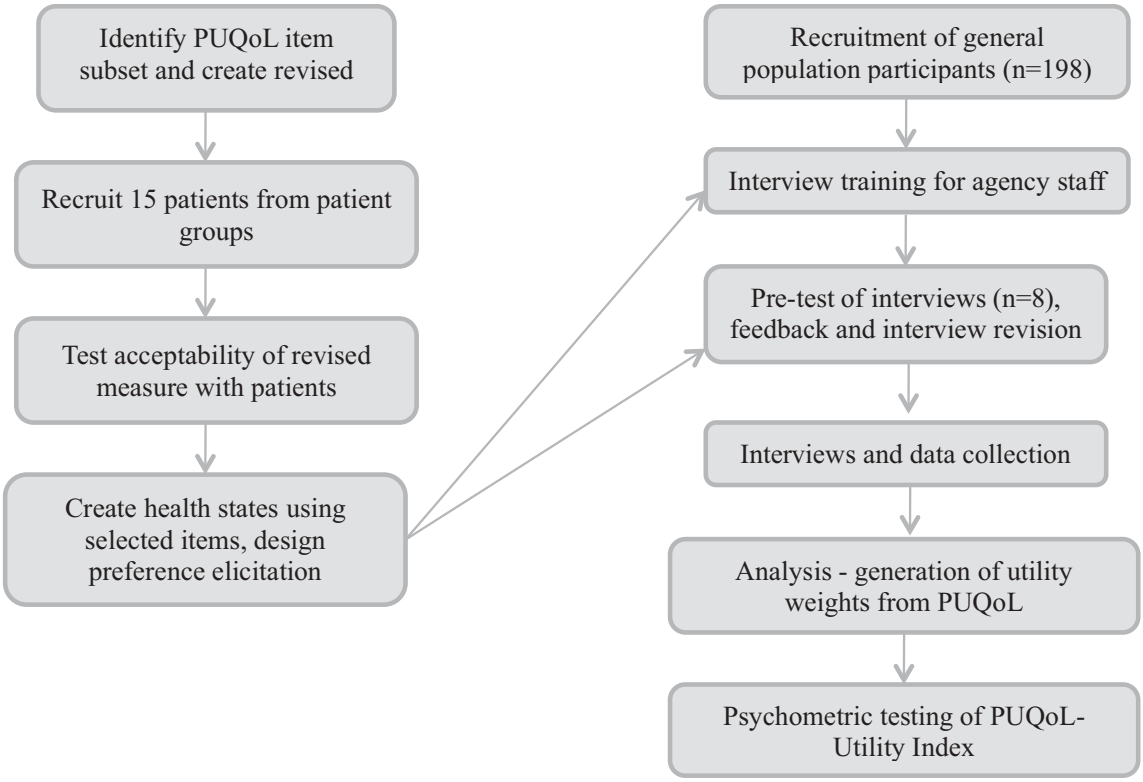
Postcode:_____ **Telephone:** _____

(When completed, original for local PI, 1 copy for CTRU, 1 copy for patient, 1 copy for patient file)

Appendix 49 Pressure Ulcer Quality of Life: Utility Index study reduced format protocol

NB: This study protocol (version 5, dated 7 Feb 2013) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to data monitoring, quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request.

Study Flow Diagram



Aims and Objectives

The overall aim of the project is to derive a preference-based utility index from the PUQoLI (the PUQoL-UI), enabling the collection of utility values from the PUQoLI and, therefore, the calculation of QALYs for the purpose of economic evaluation. Specific objectives include:

1. To check the acceptability of the revised PUQoLI with people with experience of PUs.
2. To generate PU-specific health state descriptions comprising responsive and valid PUQoLI items.
3. To conduct a preference elicitation exercise with the general population.
4. To conduct analyses establishing an algorithm and utility index scores associated with the PUQoLI item subset.

Methods

The derivation of the PUQoL-UI will follow best practice (Brazier et al, 2011). It will involve: health state generation from the reduced PUQoLI, health state valuation interviews with the general population and modelling of the health state valuations to derive the PUQoL-UI scoring tariff.

Item Selection

Prior to the start of this study it was necessary to revise and reduce the number of items in the PUQoLI. This was done using a previously collected dataset and by employing a range of statistical techniques in line with best practices (Brazier et al, 2011). A brief report describing this process is available on request.

Checking the acceptability of the revised PUQoLI

Before the health states are generated for the valuation interviews it will be necessary to check the acceptability of the revised PUQoLI with a small group of people who have experience of PUs. This will involve conducting a small number of semi-structure, face-to-face interviews with people who have (or who have had) a PU. Participants will be interviewed by an experience qualitative researcher. They will be asked to complete the revised PUQoLI and asked general questions about whether or not the questionnaire was easy to understand and complete and whether or not there were aspects or questions that were confusing. Participants will be asked specifically whether or not the new question lead-in (after the removal of the PU attribution) makes sense in each dimension. An information sheet given to people interested in the study is included in the appendix along with a consent form and an interview schedule. People with be offered £20 worth of high street vouchers for taking part in the study.

Members of the project team will review the interview responses and agree on whether or not revisions to the questionnaire are required.

Health State Generation

After any revisions to the PUQoLI have been incorporated, health state scenarios (incorporating the selected items from the revised measure) will be developed for inclusion in the preference elicitation (valuation) exercise. Health states would be generated with checks in place to ensure face validity and a range of severity is represented. An example of a hypothetical health state based on PUQoLI items is given below. The items and wording included in the final scenarios will be determined after health state sampling has been conducted and be based on the results of the interview responses.

Example pressure ulcer health state based on PUQoLI items:

Please imagine you are in the following health state:

You have a pressure ulcer and.....

You are a little bothered by throbbing pain it causes
Being kept awake by it causes you a little bother
It causes you a little bother as it limits your ability to walk
It causes a little bother as it makes it difficult for you to do your regular daily activities
You have not been bothered by fatigue from it
The concern or worry over it causes you a little bother
Having to plan going out around caring for it causes a lot of bother

Given respondent burden, it is likely that some PUQoLI constructs will have to be collapsed or will not be represented in the final valuation exercise. It is anticipated that between 25 and 50 health states will be required for the preference elicitation exercise. It is also assumed that each health state will be valued at least 20 times to ensure a robust valuation is obtained. The

selection of the health states will be based on statistical design, employing an orthogonal array.

Preference Elicitation

The preference elicitation exercise will follow NICE recommendations (NICE, 2008) and thus will mirror the methodology employed to value the EQ-5D measure. Namely, we will ask members of the UK general population to complete a series of time trade off (TTO) exercises to value the PUQoLI health states.

Valuation interviews

The interviews will be conducted by a private research organisation who are experienced in this line of work. An information sheet for the general population is included in Appendix E. Interview resources will be developed by the research team, including questionnaires, laminated cards incorporating the health state descriptions and a time-trade-off prop to aid understanding of the elicitation exercise. The draft interview schedule is included in. Interviews will be conducted face-to-face either in the person's own home, at the offices of the research agency. Respondents will also be given information regarding pressure ulcers in order that they base their interview responses on informed preferences.

The time trade-off (TTO) technique is a standard economic technique to elicit individuals' strength of preferences for various health states (Torrance et al. 1972). In the TTO, individuals choose between two certain options: full length of life (assume 20 years) in the health state to be valued, or a shorter period in 'full health' (after which they die). The amount of time (months, years) to be spent in full health is varied until the respondent can no longer easily decide which option they prefer (the point of indifference) signalling the end of the exercise. The final utility value assigned to the health state being valued is given by time spent in full health, divided by the time spent in the health state (in this case 20 years). So if the respondent was indifferent between living for 5 years in full health and 20 years in the health state being presented, the utility of that health state would be (5/20) = 0.25. The 'ping-pong' technique will be used whereby the amount of time in good health is varied until the participant reaches a point of indifference between the two choices.

The utility value of health state *i* is $h_i = 1 – (1 - h_j)x/t$ where *t* is the time in state *i* and *x* is the time of indifference.

Respondents will complete between 8-10 TTO exercises each. They will be presented with a laminated card describing a pressure-ulcer-related health state (such as the example given above) and a TTO board. The TTO board is a prop with a slide mechanism to help respondents understand the exercise and to make it easier for them to respond. The interviewer is present to make sure the respondent understands the task, to answer any queries and to record responses.

As there is a concern that the elderly may have problems in understanding and completing the TTO, we will also include a ranking exercise. In this exercise, participants will be asked to rank the PU scenario cards they considered for the TTO in order of 'severity' (the order from best-to-worst). After that they will be asked to assign a number from 0-100 to each card denoting its position on the 'health thermometer' visual analogue scale (VAS) shown in Appendix F, with 0 representing 'dead' and 100 representing 'full health'. Participants will be informed that scenarios can have equal values.

The respondents will also complete a set of questions on their general health, a socio-demographic survey and the EQ-5D measure. Interviews should last between 30-50 minutes. The Agency will offer a small incentive to participants.

Sample

Checking the acceptability of the revised PUQoLI

A sample of around 15 people who have experienced (preferably who currently have) a pressure ulcer is thought sufficient to check the acceptability of the revised PUQoLI. These will be recruited via local groups (such as Leeds Carers UK) who have agreed to participate in the study. The groups will mention the study to their members (pass on the study information sheet) who will be instructed to contact a specified member of the research team if they wish to participate. People meeting the inclusion criteria will be asked to complete a consent form and will then be able to state a location and time convenient for an interview.

Valuation interviews

The NICE guidance (NICE, 2008) states that any valuation of condition-specific measures should follow the EQ-5D valuation methodology. For this reason the sample of participants will be a representative sample of the UK general population.

Sample size

The sample size for the valuation study depends on the number of dimensions chosen for the valuation exercise – the greater the number of dimensions, the greater the sample required. It is also dependent on the number of valuations required per health state, the number of TTO valuations conducted per person and the approach taken to modelling the data.

For the analysis assuming:

- We include 8 dimensions, each with 3 levels (response options)
  = 6561 potential health states.
- We only need to value 1% (based on published valuation studies) of these health states
  = 66 states
- We need to value each a minimum of 20 times = 1320 valuations
- Each respondent can complete 8 valuations
  - Gives a sample size of 165
  - Assuming an 80% completion rate means we will require a sample of 198

Eligibility

PU sample and recruitment

Inclusion criteria

- aged ≥18 years **and**
- with experience of PU of any grade, location, or duration **and**
- able to provide informed consent to participate

Exclusion criteria

Participants will be excluded from the study if any of the following criteria apply. They:

- are unconscious or confused
- have cognitive impairment
- do not speak or understand English
- are unable to provide informed consent

The researcher will interview participants in their own home (following standard safe practice SOP). Before the interview, each participant will be given a further verbal explanation of the study by the researcher; informed that the responses they provide are made anonymous; reminded that participation is completely voluntary and that they can withdraw from the

study at any time without it affecting their care; and invited formally to participate. They will be given an opportunity to ask any questions and then if they agree to take part, the participant will be asked to sign the consent form. A copy of the consent form will be given to the participant to keep and the original copy kept by the researcher to take back to Leeds Institute of Health Sciences.

The researcher is required to utilise all possible methods to ensure that no person feels pressurised to take part in the study. This will include emphasising that participation is entirely voluntary and that participants are free to withdraw consent at any point up to, during or following the interview. The right of the person to refuse consent without giving reasons will be respected. Further, participants will remain free to withdraw from the study at any time, again, without giving reasons and without prejudicing any further treatment.

General population:

An external market research agency will be responsible for the recruitment of the general population sample. They have a group of participants on their records who regularly participate in interviews. A sample representative of the UK general population will be chosen including a spread of age, gender, educational attainment and ethnicities.

To encourage participation in the general population group, a small incentive will be offered. The research agency will be responsible for the interviewing, data recording and checking and incentive payments.

As with the patient sample, in the unlikely event that an interviewee from the general population sample becomes distressed, the interview will be stopped immediately.

Analysis

Modelling the health state valuations

It is impractical to value every health state possible in the PUQoL-UI descriptive system. Therefore, it is likely that around 0.05%-1% of the potential health states from the PUQoL-UI would be valued given the sample proposed. Those health states not directly valued by the general population will be valued indirectly using regression modelling from values attributed to health states that were included in the elicitation exercise.

Analyses will explore the two main ways to model health states: multi-attribute utility theory (MAUT) and statistical modelling (Stevens et al, 2007). A number of statistical model specifications will be explored including ordinary least squares and random effects models. Model performance will be judged using standard error statistics such as mean absolute error and root mean squared error in predicting mean health state utility values. The model with the lowest prediction errors will be selected as that to value the remaining PUQoL-UI health states. From this algorithm a scoring tariff to obtain PUQoL-UI scores from the PUQoLI questionnaires will be generated.

Ethical considerations

This study will include both members of the general population and may include elderly and highly dependent participants considered as vulnerable. Clinically in the treatment of PUs, older people are treated in the same way as younger people and it is therefore important to ensure that the study is representative of the clinical population. In addition, the interview requires the participant to reflect on their experience of having a PU and for some people this may raise topics considered to be sensitive, embarrassing or upsetting, and possibly emotionally distressing.

Ethical issues are largely related to the involvement of vulnerable adults/elderly participants with high levels of co-morbidity including acute and chronic illness. The ethical issues surrounding these potentially vulnerable participants have been addressed through the design of the recruitment process which uses local groups to help with recruitment and we will provide a caring and supportive environment in which to discuss any sensitive issues that may arise. If the participant becomes distressed during the interview or from completing the questionnaire, then the interview will be immediately stopped. It will be stressed to all participants that they are able to withdrawn from participation at any time without giving reason.

No treatments or procedures are incorporated into the PUQALY study design so there is minimal risk to the participant sample. Participants will be made aware that they free to leave the study or discontinue the elicitation interviews at any time.

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000. Informed written consent will be obtained prior to involvement into the study. The right of a person to refuse participation without giving reasons will be respected. The participant will remain free to withdraw at any time from the study without giving reasons.

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Appendix 50 Pressure Ulcer Quality of Life: Utility Index general population valuation study information leaflet

Quality of life in people with pressure ulcers (bed sores)

You are being invited to take part in a research study. Before you decide whether or not to take part, we would like to explain the reason for the research and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Contact us:

Research Agency contact details

What is the purpose of the study?

Pressure ulcers (bed sores) happen to people with poor health who are unable to move about much. The Department of Health have set out to make sure that a lot less people will get pressure ulcers in the future. The University of Leeds has been involved in a large research study with people who have pressure ulcers. As part of this we have developed a new questionnaire that measures the impact of pressure ulcers on a person's quality of life. This is based on the kinds of problems people with pressure ulcers have, for example pain and discomfort, unpleasant smell and so on.

To help us understand how severe the aspects measured by the questionnaire are we need to ask people from the general population (i.e. people who do not have pressure ulcers) to answer some questions relating to scenarios described by the questionnaire. The information we get from these questions will enable us to generate scores from the questionnaire that – after completion by patients participating in clinical trials – will help determine which new pressure ulcer treatments are best value for money in the future. The research agency are a private company and are conducting the research on behalf of the University of Leeds.

What will be involved if I agree to take part in the study?

If you would like to participate in the study please contact the research agency whose telephone number and email address is at the front of this information sheet. As part of this study the researcher will ask you to complete a questionnaire about you and your health and then conduct a number of tasks based around scenarios from the pressure ulcer questionnaire. The whole process will take about 30-40 minutes.

Do I have to take part in the study?

No. It is up to you to decide if you want to take part in the study. If you think you want to take part and then change your mind you can without giving a reason.

When and where will the study take place?

The interview will be at a time that suits you and will be at your home (or at research agency premises).

Will the information obtained in the study be confidential?

Yes. It will not be possible to connect your answers in the questionnaires to the report. The questionnaires and interview responses will have a number and not a name to identify them for the researchers.

Will anyone else be told about my participation in the study?

No. We will not contact and tell anyone else about your participation.

Who is funding this study?

The research agency is being paid to conduct the work by the University of Leeds. The University of Leeds was funded to conduct the research by the Department of Health through the National Institute of Health Research.

What if I wish to complain about the way in which this study has been conducted?

If you have any complaints or concerns please contact the research agency in the first instance using the contact details on the front page. If you feel your complaint has not been satisfactorily dealt with then please contact the project co-ordinator at the University of Leeds (Karen Vinall-Collier; Email: K.A.Vinall@leeds.ac.uk; Telephone: 0113 343 0861).

Appendix 51 Pressure Ulcer Quality of Life: Utility Index valuation study interview schedule

Today's date: ☐☐ ☐☐ ☐☐☐☐ (d d m m y y y y) Participant ID: ☐☐☐ / ☐☐☐ (Cen / Pat)

PUQALY – Valuing quality of life after pressure ulcers

Interview Schedule A

Please read out to the participant:

"*Thank you for agreeing to participate in this research. The research aims to help better understand how pressure ulcers impact on people's quality of life. During the interview you will be asked a number of questions that aim to get you thinking about how severe the impact of pressure ulcers are and ways in which they can affect on an individual's life"*

...Please answer all of the questions you feel able to. There are no right or wrong answers. All of your responses are anonymous and confidential and ***will not*** *affect any treatment you receive in the future. The interview should last about 30-45 minutes. However, you are free to stop the interview at any time and withdraw from the study. Please ask for clarification if you do not understand a question*"

Section 1: Demographic questions

1. What is your date of birth? ☐☐ ☐☐ ☐☐☐☐ d d m m y y y y

2. Are you? (*please tick one*): ❑ Male ❑ Female

3. How many children do you have (under 18)? ☐☐

4. Which ethnic group do you belong to? *(please tick only one)*

- ❑ White
- ❑ Asian or Asian British
- ❑ Black or Black British
- ❑ Chinese
- ❑ Mixed ethnicity
- ❑ Gypsy / traveller
- ❑ Other ethnic group

5. What is the highest level of education you have completed? *(please tick only one)*

- University or college or equivalent ❑
- Intermediate between secondary level and university (e.g. technical training) ❑
- Secondary school ❑
- Primary school (or less) ❑

Section 2: Health questions

6. Do you have any medical conditions, illnesses or disabilities?

❑ Yes ❑ No

Do you currently have, or have you had, any of the following health conditions? **CIRCLE AS MANY ANSWERS AS ARE APPROPRIATE FOR YOU**

1. Arthritis
2. Cancer
3. Chronic Obstructive Pulmonary Disease
4. Diabetes
5. Heart disease
6. Hypertension
7. Stroke
8. Depression
9. Other mental health conditions
10. Other health conditions
11. None of these conditions

Other please list:

7. How would you rate your overall health at the moment? *(Please tick one)*

Very poor	Poor	Fair	Good	Very good
❑	❑	❑	❑	❑

Section 3: Time Trade Off

Test TTO

"I'm going to ask you to complete a task called 'Time-trade-off' which will tell us how bad you think it would be to live with pressure ulcers of varying severity. I'm going to ask you to complete a series of [9-11] TTO questions. In each case I'm going to show you a health situation on a card describing different effects and severity of pressure ulcers (also known as bed sores). Although they look similar, each scenario is different in some way. The other card is called full health and is Life A and is represented on a pink card The health condition with pressure ulcers in called Life B and is represented on green cards. . Full health is defined here as not having any bother with the health problems described on the green cards.
Although it sounds strange, in this hypothetical task I want you to imagine that you only have 10 years to live."

Show participant Scenario Green Card life B

"I'd like you to imagine that you were living in this health scenario and you had to live in it for the last 10 years of your life. Then I want you to imagine that you have a choice: you can either live in the scenario described in Life B for those remaining 10 years of your life or you can live for a shorter period of time, for example 5 years, but without the health problems described in Life A. So if you had 10 years left to live, would you prefer to live for those 10 years in the situation on card X or for 5 years but in normal health? (after the fifth year you would die)"

Use the ping-pong method from this point on to arrive at the participant's point of indifference as per training received.

Please ask participant to complete the [8-9] TTO tasks/cards

(The screen has the colours pink for full health and green for the pressure ulcer health state)

"*First I'd like to ask you to make a choice between Full health which is life A (read out if required pink card A) and the life with a pressure ulcer which we have called life B (on the green card). On the computer screen, the two scales show the number of years you would live in each health state.*

Q 1 At the moment, each scale says 10 years. This means that you would either live in Life A for 10 years and then die or you would live in Life B for 10 years and then die. Would you prefer Life A or Life B or are they the same?

- If Life A is chosen go to Q 4
- If Life B is chosen go to Q 2
- If it is the same go to Q 3

Q 2 Does this mean that you would rather live in Life B for 10 years than in Life A for 10 years?

- If yes, save the values 10 for the Full Health and 10 years for the Health State x, (are they timed – if so then start a new clock)
- If no (first time) repeat Q 1
- If no (second time after repeating Q1) go to Q 4

Q 3 Does this mean that living in Life B for 10 years would be the same as living in Life A for 10 years?

- If yes, save the values (10 years for the Full Health and 10 years for Health State X, (if timed clock stops and new card)
- If no (first time) repeat Q 1
- If no (second time) go to Q 4

Q 4 Now you would either die immediately, or you would life in Life B for 10 years and then die. Would you prefer to die immediately or to live Life B, or are they the same?
(the screen shows Life A at 0 years and Life B at 10 years)
Choice of Life A; Life B: or The same

- If Life A, go to Q 9
- If Life B, go to Q 5

- If the same, save the values (0 for Full health and 10 years for Health State x) (Stop and start a new card)

Q 5 Now you would either live in Life A for 5 years and then die or you would live in Life B for 10 years and then die. Would you prefer Life A or Life B, or they the same?
(The screen shows Life A at 5 years and Life B at 10 years)

- If Life A, the cursor will move one notch to the left becoming 4 years. Go to Q6.
- If Life B, the cursor will move one notch to the right i.e. becoming 6 years. Go to Q7.
- If the same, save the values 5 years for Full health and 10 years for health state X. Stop and start a new TTO exercise card.

Q 6 Now you would either live in Life A for (updated number) years and then die or you would live in Life B for 10 years and then die or are they the same?

- If Life A, the cursor will move one notch to the left. Repeat Q 6 until the respondent answers "Life B" or the "Same". If the marker is at zero, repeat Q6, if Life A is chosen go to Q 9 (the cursor can go further to the left), if Life B is chosen do the second bullet point of Q 6, if the same do the third bullet point of Q6
- If Life B is chosen, the cursor will move one half notch to the right. Go to Q 8
- If the same, save the values (updated number from screen) years and 10 years for health state x, stop and start new TTO card.

Q7. Now you would either live in Life A for (updated number) years and then die or you would live in Life B for 10 years and then die, Would you prefer Life A or Life B or are they the same?

- If Life A, the cursor will move one half notch to the left, go to Q8.
- If Life B, the cursor will move one notch to the right. Repeat Q7 until
    a. If respondent answers "Life A GO TO Q8. If the respondent answers "Same" – save the value and start a new TTO exercise Card.
    b. If respondent answers Life B and the marker is on 9 years then the marker moves up to 9 years 3 months, 9 years 6 months, 9 years 9 months, 9 years 11 months.
- If the same, save the values (updated number) for Full Health and 10 years for health state x), Stop and start a new TTO exercise.

Q8. Now you would either life in Life A for (updated number) of years and then die or you would life in Life B for 10 years and then die. Would you prefer to have Life B or are they the same?

- If Life A, save the values (updated number in years and months) for Full Health and 10 years for Health State x, stop and start a new TTO exercise.
- If Life B, save the values (updated number in years and months) for Full Health and 10 years for Health State x. Stop and start a new TTO exercise.
- If "same", save the values (updated number in years and months) for Full Health and 10 years for Health State x) Stop and start a new TTO exercise.

Q 9 (If always choose Life A) Does this mean that you would rather die immediately than life in Life B for 10 years?

- If yes go to Q11
- If no go to Q 4.

Q10 (If always chooses Life B) What if you would either live in Life A for 9 years 3,6,9,11 months and then die or live in Life B for 10 years? Would you prefer Life A or Life B or are they the same?

- If Life A, save the values (updated number) for Full Health and 10 years for Health State X. Stop and start a new TTO exercise.
- If Life B, save the values (updated number in years and months) for Full Health and 10 years for Health State x. Stop and start a new TTO exercise.
- If "same", save the values (updated number in years and months) for Full Health and 10 years for Health State x) Stop and start a new TTO exercise
  for Health State x. Stop and start a new TTO exercise.

TTO answer table

Scenario	TTO response – point of indifference (years, months)
1	
2	
3	
4	

5	
6	
7	
8	
9	
10	
11	

Did the participant appear to understand the TTO?

❑ Yes ❑ No ❑ Unsure

Section 4: Ranking task

Please take a look at the scenario cards; these are the scenarios you have just been considering in the time trade-off task. We have added to scenarios to this – one is 'death' and one is your own health state at the moment.

We would like you to think about these health scenarios and try to put them i in order of severity – i.e. arrange the cards so that they range from the most severe to the least severe in your opinion.

When you have sorted the cards please enter the order of the scenario cards onto the computer.

Now I would like you to rate the severity of each scenario from 0 to 100 with 0 being the worst health you can imagine and 100 representing Full health. If you think that two scenarios would have the same score then that is fine. Please enter the values you gave for each scenario onto the computer.

Please make a note of the order and rating for each scenario

Scenario	Ranking (1-12 or13) 1 is worst	Rating (0-100)
1		
2		
3		
4		

5		
6		
7		
8		
9		
10		
11		
Death		
Own health state		

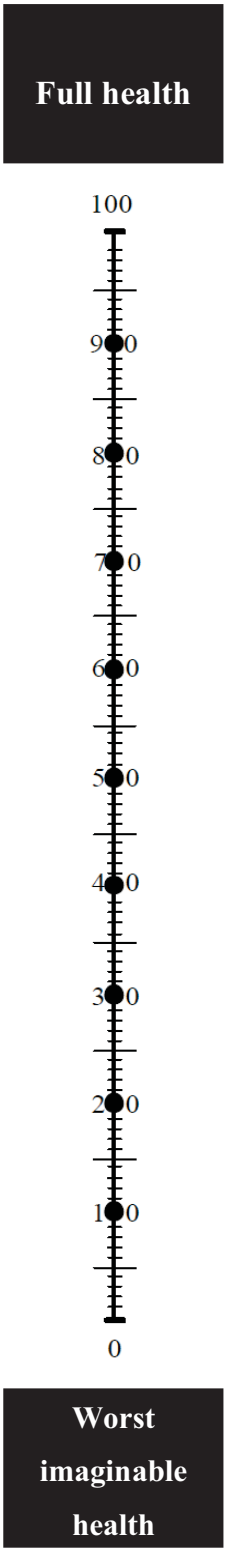
Did the participant appear to understand the ranking task?

❑ Yes ❑ No ❑ Unsure

Section 5: EQ-5D

[NB: The EQ-5D instrument was collected however the instrument is omitted due to copyright. The EQ-5D instrument can be obtained from URL: http://www.euroqol.org/*].*

Health rating scale

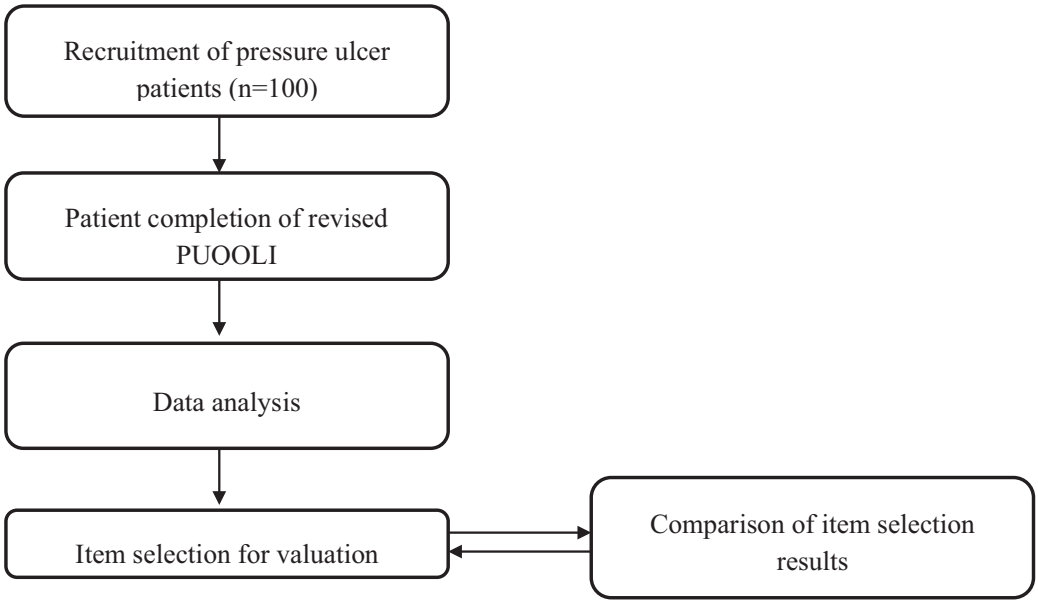


Thank participant for helping with the research and reiterate assurances about confidentiality and anonymity. Ask if they have any questions.

Appendix 52 Pressure Ulcer Quality of Life: Utility Index methodology study reduced format protocol

NB: This study protocol (version 6, dated 13 Jun 2013) is in a reduced format including only the study aims, methods and ethical considerations. Sections pertaining to study background have been removed as they are included as a chapter section. Information pertaining to data monitoring, quality assurance, confidentiality, archiving, statement of indemnity, study organisational structure, funding, and publication policy are available upon request.

Study Flow Diagram



Aims and Objectives

The overall aim of the project is to generate data using the revised version of the PUQoLI measure to enable item reduction analysis and a comparison of item selection methods.

1. To generate data on the new PUQoLI via a patient survey.
2. Conduct item selection analysis using the data.
3. Compare the items selected for the reduced PUQoLI from this and previous analyses.
4. Conduct additional methodological work such as mapping from the EQ-5D and from time-trade off values to the revised PUQoLI.

Methods

Item Selection and Health State Generation

A sample of patients with PUs will complete the interview administered measure either in hospital or in the community. In order that we are able to compare the item selection results across studies, the samples that provide the data have to be comparable in terms of PU severity, demographics (i.e. age and gender) and location of the participant (community or hospital). Sample size is not critical as it will be possible to randomly select a subsample from the original dataset (and rerun the analysis) to match the – likely - smaller dataset we will generate from this study.

The sample used for the original item selection are shown in the table below:

N = 229	N (%)
Gender	
Male	119 (52%)
Female	110 (48%)
Age	
Under 70 years	90 (39.5%)
70 years and over	138 (60.5%)
PU grade	
Superficial	115 (50%)
Severe	94 (41%)
Mixed	20 (9%)
Setting	
Hospital	141 (62%)
Community	88 (38%)

Sample size

The sample size is dependent on that required to obtain robust estimates from the Rasch analysis. Linacre (1994) proposed that for most purposes a sample size of 150 (n range, 108-243) will provide 99% confidence of item calibration of +/-0.5 logits and a sample size of 100 (n range, 64-144) will provide 95% confidence of item calibration within +/-0.5 logits. In this study we will aim for 95% confidence and therefore a sample of 100 patients.

Eligibility and Recruitment

Members of the tissue viability team (TVT) which includes the local Principal Investigator, tissue viability nurse specialists, nurse consultants, and other members of their local clinical team (i.e. tissue viability and clinical research nurses) at participating trusts will identify potential patients.

Eligibility

Patients from participating acute and community NHS Trusts, with existing PUs, will be included in the study if they are hospital in-patients or outpatients, intermediate care patients, or community patients under the care of community care nursing services, and they fulfil the criteria detailed below. We will ensure representation of patients from all PU categories (Categories 1-4/U) and treatment types. Consecutive patients will be identified from each PU category and approached to participate. Recruitment will continue on a rolling basis until a minimum of 10 patients from each PU group are recruited and interviewed.

Inclusion criteria

- aged ≥18 years **and**
- with an existing PU of any grade, location, or duration **and**

  Give their written informed consent/verbal witnessed consent Exclusion criteria

Patients will be excluded from the study if any of the following criteria apply. They:

- have only moisture lesions
- are unconscious or confused
- have cognitive impairment
- do not speak or understand English
- they do not have an existing PU **or**
- are unable to provide informed consent

Patients who are deemed ethically inappropriate to approach by members of the TVT, for example, those where death is imminent (any patient who is on or meets the criteria of the Liverpool Care Pathway for the dying) will not be approached.

To clarify, those not deemed ethically appropriate is a clinical judgement about the appropriateness of approaching patients who are very seriously ill or distraught. For example,

patients where death is imminent (any patient who is on or meets the criteria of the Liverpool Care Pathway for the dying) will not be approached or in other circumstances (personal to that patient) where it is considered inappropriate (for example, distraught due to a recent bereavement).

In addition the assessment of capacity will relate specifically to decisions pertaining to this particular research project. Each patient will be assumed to have capacity unless it is established that they lack capacity. Ward/community based nurses identifying patients for study participation, will be asked to consider aspects of capacity before any approach to patients is made and during the information giving stage prior to consent. The TVT member will assess the patient's ability to understand what decisions they need to make and why; the consequences of the decision to participate; their ability to understand, use and retain the information related to the decision to participate and be able to communicate their decisions effectively (as specified in the Mental Capacity Act 2005) If there is any concern about capacity the TVT member will consult with other members of the attending clinical team and/or relative/carer/friend (as appropriate) and a decision will be made with the attending clinical team/relative/carer/friend as to whether the patient is able to provide written consent.

Recruitment and consent procedures

Potential participants will be identified by the direct care team from their local area of practice. A record of those identified as eligible, approached to participate, refusals, consenting patients and questionnaire returns will be made. A verbal explanation of the study and Patient Information Leaflet will be provided by the TVT member for the patient to consider. This will include details about the rationale, design, and personal implications of the study.

Following information provision, patients will have as long as they need to consider participation and will be given the opportunity to discuss the study with their family and other healthcare professionals before they decide whether they would be willing to take part in the study. Assenting patients will then be invited to provide informed, written consent. Should the patient be capable of giving consent but are physically unable to complete the written aspects of the consent form, witnessed consent should be obtained using the Witnessed Consent Form. An appropriate witness would be a family member or friend of the

patient, or another member of the patient's healthcare team who is not directly involved in the research study.

The researcher is required to utilise all possible methods to ensure that no patient feels pressurised to take part in the study. This will include emphasising that participation is entirely voluntary and that participants are free to withdraw consent at any point up to, during or following the survey. The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time, without giving reasons and without prejudicing any further treatment. After signing the consent form patients will be handed the questionnaire schedule to complete.

To clarify, potential participants will be identified by the direct care team from their local area of practice. The direct care team includes ward and community staff. For some patients the direct care team also includes members of the Tissue Viability Team (i.e. if the patient is under the care of the Nurse Consultant/Nurse Specialist, they are part of the direct care team).

Where the patient is not under the care of the Tissue Viability Team, ward/community staff will identify potential participants, and obtain verbal assent for a visit by the Tissue Viability Team (Nurse Consultant/Specialist/Research Nurse) to discuss the possibility of study participation and flag the patient to the Tissue Viability Team.

Where the patient is under the care of the Tissue Viability Team (Nurse Consultant/Specialist) they will either discuss study participation with the patient (providing a full verbal explanation of the study and Patient Information Leaflet) or obtain verbal assent for a visit by the Research Nurse.

Registration

Patients will be registered with the CTRU following informed consent and confirmation of eligibility. The CTRU will issue a study identification number which includes centre code. Registration will include centre, confirmation of eligibility, confirmation of consent, date of birth, gender, PU grade and patient location (community or hospital). The data will be used for central monitoring of recruitment. CTRU will also be responsible for accrual recording with the NIHR.

Screening

The TVT member will complete a log of all patients screened for eligibility who are not registered either because they are ineligible or because they declined participation. All anonymised screening logs will be returned to the AUHE.

Anonymised information will be collected including:

- The reason not eligible for study participation or
- Eligible but declined
- Date of Birth
- Gender
- Ethnicity
- Pressure ulcer grade and location

Survey

The survey will be administered by a research nurse. The surveys will be completed in the out-patient clinic, in-patient ward or in the community as determined by the patient's circumstances and preferences at the time.

Study participants will complete the revised PUQoLI, the EQ-5D (a five-item health-related quality of life questionnaire) and EQ-VAS (a 0-100 health rating scale) (EuroQoL, 1990) and a set of socio-demographic and PU-related questions. They will also complete a paper version (Robinson, 2010) of the time trade off (TTO) task (Torrance, 1972). The TTO asks about how much time the patient would be willing to trade off in exchanging their current health status for full health. This will provide additional useful information in valuing the PUQoLI.

It is anticipated that the survey will take approximately 25 minutes to complete. A user manual for the PUQoLI is available and should be used with any queries relating to completion of that measure.

Analysis

Item selection

In the first instance, one item representing each of the ten PUQoL instrument constructs will be chosen. Items will be selected on the basis of traditional psychometric analyses and Rasch analyses.

Rasch analysis (Rasch, 1961) is now seen as the method of choice for the development and improvement of questionnaires as it has several advantages over Classical Test Theory approaches such as factor analysis (Wright, 1996; Wright and Tennant, 1996; Luquet et al., Prieto et al., 2003; Tennant et al., 2004; Waugh and Chapman, 2005; Nijsten et al., 2006a). Rasch is often the method employed to identify reduced forms of measures that will be used in preference valuation studies. (e.g. Brazier et al 2012; Kowalski et al, 2012; Mulhern et al, 2012) The Rasch model is a simple logistic latent trait Item Response Theory model. Rasch analysis places response data for each individual and each item on the same spectrum of severity (logit scale). According to the model, the probability that an individual will respond in a certain way to a particular item is a logistic function of the relative distance between the item location (parameter) and the person location (parameter), and only a function of these two factors. Persons and items are plotted on the same logit scale on the basis of the difference in their location on the underlying spectrum. This difference governs the probability of the expected response for a person, of a given severity, on a question of a given severity. If the observed data do not deviate significantly from the expected responses, then the items fit the Rasch model.

Criteria for item selection:

Rasch measurement method analyses –

- Degree of fit to the Rasch model (Rasch, 1961) – Chi^2 probability and fit residual (items with non-significant Chi^2 and residuals $<\pm 2.5$ are candidates)
- Differential item functioning (DIF) based on age and gender such that bias by these factors is minimised (items with no DIF are candidates)
- Item logit position on each construct's measurement continuum such that items with a range of severity (spanning the entire measurement range) can be identified (items that collectively represent a wide spread of the latent trait are candidates)
- Disordered response category thresholds (items with correctly functioning response categories are candidates)

Traditional psychometric analyses –

- Distribution of scores and presence of floor/ceiling effects (items with no floor/ceiling effect are candidates)
- Item-to-total correlation (items with ITC 0.2-0.8 are candidates)
- Principal components factor analyses (items having a moderate-high factor loading within a subscale being candidates)
- Ability to discriminate between pressure ulcer severity groups – T-tests for superficial vs severe PU patient scores (highly discriminatory items are candidates)
- Pearson correlations with EQ-5D and global PUQoL-I item ("How would you rate your overall QoL because of your pressure sore(s)") (items with moderate-high correlations are candidates)

The final selection of items will be compared with those selected from earlier analyses (and based on the PU-attributable data). The performance of each in terms of the above criteria will be described and compared across analyses.

Mapping analysis

In addition to the item selection analysis we will also conduct a mapping analysis (Brazier et al, 2010) whereby regression techniques are employed to predict the EQ-5D scores and TTO responses using responses on the PUQoLI (and other factors such as age and gender).

This would generate an algorithm that would allow the indirect estimation of utility values from the PUQoLI.

Data Monitoring

Data will be monitored for quality and completeness by the project team (PT). The PT will liaise with nurses to ensure that the sample recruited matches as far possible that used for the original analyses. The proportion of males/females, different PU grade and location (hospital/community) of recruited patients will be monitored to enable this.

Ethical considerations

This study will include elderly and highly dependent patients considered as vulnerable. Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with

high levels of co-morbidity including acute and chronic illness. Clinically, older patients are treated in the same way as younger patients and it is therefore important to ensure that the study is representative of the clinical population. In addition, the survey requires the patient to reflect on their experience of having a PU and for some people this may raise topics considered to be sensitive, embarrassing or upsetting, and possibly emotionally distressing.

Ethical issues are largely related to the involvement of vulnerable adults/elderly patients with high levels of co-morbidity including acute and chronic illness. The ethical issues surrounding these potentially vulnerable patients have been addressed through the design of the recruitment process which uses local staff and includes experienced clinical nurses to help with recruitment and we will provide a caring and supportive environment in which to discuss any sensitive issues that may arise. If the patient becomes distressed during survey completion, then the nurse will immediately stop the interview/survey. It will be stressed to all patients that they are able to withdraw from participation at any time without giving reason, and without any effect on their care. They will be referred back to their treating nurse specialist if required.

No treatments or procedures are incorporated into the PUQALY study design so there is minimal risk to the patient sample. Participants will be made aware that they free to leave the study or discontinue at any time without their future care being affected.

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, October 2000. Informed written consent will be obtained prior to involvement into the study. The right of a patient to refuse participation without giving reasons will be respected. The study will be submitted to and approved by a main Research Ethics Committee (main REC) and the appropriate Site Specific Assessor for each participating centre prior to entering patients into the study. The PT will provide the main REC with a copy of the final protocol, patient information sheets, consent forms and all other relevant study documentation.

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Appendix 53 Pressure Ulcer Quality of Life: Utility Index methodology study patient information sheet and consent form

PURPOSE

Pressure ulcer quality adjusted life years (PUQALY): an item reduction survey

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Principle investigator: Professor Claire Hulme

Contact us:

Researcher: **Karen Vinall-Collier** **Leeds institute of** **Health Sciences** **University of Leeds** **Clarendon Road** **Leeds** K.A.Vinall@leeds.ac.uk **0113 343 0861**	**Researcher:** **David Meads** **Leeds institute of** **Health Sciences** **University of Leeds** **Clarendon Road** **Leeds** d.meads@leeds.ac.uk **0113 343 0860**	**Insert details of local R&D contact here:**

What is the purpose of the study?

Pressure ulcers (bed sores) happen to people with poor health who are unable to move about much. The Department of Health want to try and make sure that a lot fewer people get pressure ulcers in the future. The University of Leeds has been involved in a large research study with people who have pressure ulcers. As part of this we have developed a new questionnaire that measures the impact of pressure ulcers on a person's quality of life. This is based on the kinds of problems people with pressure ulcers have, for example pain and discomfort, unpleasant smell and so on. It is important for us to find out which of these problems affect people with pressure ulcers most. We would like your help in testing this new questionnaire. This will help measure which new treatments are best value for money in the future.

What do I have to do if I agree to take part in the study?

If you agree to take part the nurse will ask you to complete a survey. The survey asks about you pressure ulcer and your quality of life and should take about 20-30 minutes to complete. Having an ulcer impacts on health and how people get by in their lives. The questions are designed to help us understand this better.

Do I have to take part in the study?

No. It is up to you to decide if you want to take part in the study. If you decide to take part you will be asked to sign a consent form. If you think you want to take part and then change your mind you can without giving a reason. This will not make any difference to the medical care you receive.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, family member, or member of your healthcare team. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

When and where will the study take place?

Study participation will be at a time that suits you and will be either at your home or in the hospital if you are still a patient. This will be a 'one off' and you will not be asked to

participate again for this study. If you are in hospital you can complete the survey there but if you prefer to complete it at home then the nurse will give you a survey pack which includes a reply-paid envelope so you can post back your completed questionnaires.

What other information will be collected in the study?

We may also ask you about your pressure ulcer and about your general health.

Will there be any effects on my treatment?

No. Your treatment will be the same whether you take part or not.

Will the information obtained in the study be confidential?

Yes. It will not be possible to connect your answers in the questionnaires to the report we write about the study. The questionnaires will have a number and not a name to identify them for the researchers. The completed questionnaires will be kept secure and stored in our locked cupboards at the University.

Will anyone else be told about my participation in the study?

It is usual in studies to let your family doctor know that you have taken part in a study. We will check this with you first.

Who is funding this study?

The money to pay for this study has come from the department of health through the National Institute of Health Research.

What if I wish to complain about the way in which this study has been conducted?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not affected in any way because you have taken part in a research study.

If you have any complaints or concerns please contact the project co-ordinator (Karen Vinall-Collier). Otherwise you can contact David Meads.

Our contact details are on the front of this leaflet.

[delete this line and print on headed paper]

PARTICIPANT CONSENT FORM

Pressure ulcer quality adjusted life years (PUQALY): An item reduction survey

The participant should complete the whole of this sheet himself/herself

	Please confirm the statements by putting your initials in the box below
I have read and understood the participant information sheet, dated 20.6.13. I have had the opportunity to ask questions and discuss this study. I have received satisfactory answers to all of my questions.	
I understand that I am free to withdraw from the study at any time and without having to give a reason. The relationship with my healthcare providers, level of services received or my legal rights will not be affected.	
I understand that if I decide to drop out of the study in the middle of the interview my questionnaire will be destroyed.	
I understand that any information I provide, including personal details, will be confidential, stored securely and only accessed by those carrying out the study.	
I understand that any information I give may be included in published documents but it will not be possible to identify me personally.	
I agree to take part in this study.	
Participant Signature …… Date:	
Researcher Signature …… Date:	

Thank you for agreeing to take part in this study

Appendix 54 Pressure Ulcer Quality of Life: Utility Index methodology study patient questionnaire

Pressure Ulcer Quality Adjusted Life Years (PUQALY): An Item Reduction Survey

***To the Researcher*:**

This survey should administered by you to the patient. Please read out the questions and record their responses. Sections A and B ask about the patient and their health. Section C is related to quality of life and Section D asks about health preferences.

Please provide clarifications and explanations of questions if they are not clear to the patient. However, the responses should be those of the patient. Please refer to the PUQoLI user manual if necessary.

Researcher to read out to the patient:

Thank you for agreeing to participate in this research. The research aims to help better understand how pressure ulcers impact on people's quality of life. This survey asks a number of questions that aim to get you thinking about the impact of your pressure ulcer(s) and ways in which they affect your life.

Please answer all of the questions you feel able to. There are no right or wrong answers. All of your responses are anonymous and confidential and will not affect any treatment you receive in the future. The survey should take about 20-30 minutes to complete. However, you are free to stop participating at any time and withdraw from the study. Please ask for clarification if you do not understand a question

Section A: About You

1. Patient's date of birth ☐☐ ☐☐ ☐☐☐☐ d d m m y y y y

2. Gender (*please tick one*): ❑ Male ❑ Female

3. How many children do you have (under 18)? ☐☐

4. Which ethnic group do you belong to? *(please tick only one)*

❑ White
❑ Asian or Asian British
❑ Black or Black British
❑ Chinese
❑ Mixed ethnicity
❑ Other ethnic group

5. What is the highest level of education you have completed? *(please tick only one)*

University or college or equivalent ❑
Intermediate between secondary level and university (e.g. technical training) ❑
Secondary school ❑
Primary school (or less) ❑

Section B: Your Health

1. Do you have any medical conditions, illnesses or disabilities?

❑ Yes ❑ No

If 'Yes', please list your other illnesses or disabilities:

.....

.....

.....

2. Are you a wheelchair user?

❑ Yes ❑ No

3. How long have you had your pressure ulcer(s)?

	Weeks		Months		Years
☐		☐		☐	

4. On which part of your body do you have pressure ulcer(s)?
(*please tick*)

Area at the bottom of your spine	❑	Ankle/Foot	❑
Buttocks	❑	Heel	❑
Back of leg and/or thigh	❑	Elbow	❑
Hip	❑	Head and/or face	❑

Other ❑ Please specify: ☐

5. What is the patient's clinical pressure ulcer grade? *(Please tick one)*

Grade 1	Grade 2	Grade 3	Grade 4
❑	❑	❑	❑

6. How severe would you say your pressure ulcer(s) are at the moment? *(Please tick one)*

Very severe	severe	Moderate	Mild	Very mild
❑	❑	❑	❑	❑

7. Apart from your pressure ulcer do you have any other type of wounds or ulcers (such as diabetic foot ulcer or venous leg wound) at the moment?

Yes ❑ No ❑

8. Thinking about your health (including your pressure ulcer(s) and all other health problems). How would you rate your overall health at the moment? *(Please tick one)*

Very poor	Poor	Fair	Good	Very good
❑	❑	❑	❑	❑

9. Please now **imagine** that you did not have a pressure ulcer. How would you rate your health at the moment if you did not have the pressure ulcer (but still had the other health problems)? *(Please tick one)*

Very poor	Poor	Fair	Good	Very good
❑	❑	❑	❑	❑

Section C: Quality of Life

In this section please complete the following questions which ask about your general health and your pressure sore(s) and how they have affected aspects of your everyday life over the past week.

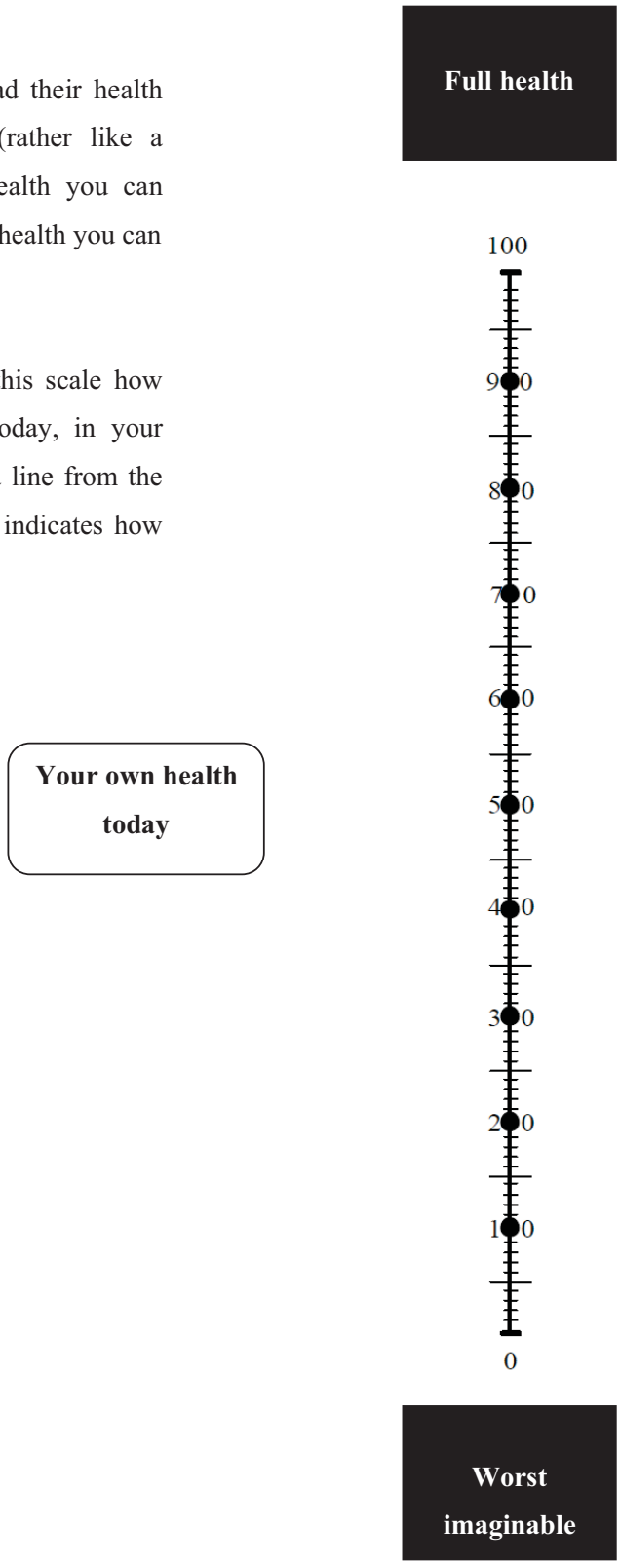
[NB: The PU-QOL instrument was collected however the instrument is omitted due to copyright. The PU-QOL instrument can be obtained from URL: http://medhealth.leeds.ac.uk/puqol-ques*].*

[NB: The PUQOL-UI instrument was collected however the instrument is omitted due to copyright. The PUQOL-UI instrument can be obtained from URL: http://ctru.leeds.ac.uk/purpose*].*

Health rating scale

To help people say how good or bad their health state is we have drawn a scale (rather like a thermometer) on which the best health you can imagine is marked 100 and the worst health you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box to whichever point on the scale indicates how good or bad your health is today.



Section D: Your health preferences

This next section includes an **imaginary** exercise. Even though the questions may sound strange please do your best to answer. Your responses will give us an idea about how severe your current health problems are.

[*to be read by the researcher*]

For each question **imagine** that you have all your current health problems and are guaranteed to live for another ten years after which you would die or you could choose to live in full health but for less than 10 years.

For each set of options please tick **one** box to indicate which you would prefer.

1.	To live 10 years in your current health	❑		7.	To live 10 years in your current health	❑
	To live 9 years and 9 months in full health	❑			To live 5 years in full health	❑
2.	To live 10 years in your current health	❑		8.	To live 10 years in your current health	❑
	To live 9 years and 6 months in full health	❑			To live 4 years in full health	❑
3.	To live 10 years in your current health	❑		9.	To live 10 years in your current health	❑
	To live 9 years in full health	❑			To live 3 years in full health	❑
4.	To live 10 years in your current health	❑		10.	To live 10 years in your current health	❑
	To live 8 years in full health	❑			To live 2 years in full health	❑
5.	To live 10 years in your current health	❑		11.	To live 10 years in your current health	❑
	To live 7 years in full health	❑			To live 1 year in full health	❑

6.	To live 10 years in your current health	❑		12.	To live 10 years in your current health	❑
	To live 6 years in full health	❑			To live 6 months in full health	❑

If the patient gives an alternative amount of time please write this here:

.....

Please tick here if the patient did not understand this task: ❑

For each question below **imagine** that your pressure ulcer had been cured. Then imagine that you have the choice between living for the next 10 years in your current health with your health problems but without a pressure ulcer (after which you would die) or living fewer years but in full health (after which you would die).

For each set of options please tick **one** box to indicate which you would prefer

1.	To live 10 years in your current health	❑		7.	To live 10 years in your current health	❑
	To live 9 years and 9 months in full health	❑			To live 5 years in full health	❑
2.	To live 10 years in your current health	❑		8.	To live 10 years in your current health	❑
	To live 9 years and 6 months in full health	❑			To live 4 years in full health	❑
3.	To live 10 years in your current health	❑		9.	To live 10 years in your current health	❑
	To live 9 years in full health	❑			To live 3 years in full health	❑
4.	To live 10 years in your current health	❑		10.	To live 10 years in your current health	❑

	To live 8 years in full health	❑			To live 2 years in full health	❑
5.	To live 10 years in your current health	❑		11.	To live 10 years in your current health	❑
	To live 7 years in full health	❑			To live 1 year in full health	❑
6.	To live 10 years in your current health	❑		12.	To live 10 years in your current health	❑
	To live 6 years in full health	❑			To live 6 months in full health	❑

If the patient gives an alternative amount of time please write this here:

.....

Please tick here if the patient did not understand this task: ❑

Thank participant for completing this survey and helping with our research

Appendix 55 Original application

Patient and public involvement section

Summary of proposal funded

We planned to ensure PPI via service user membership of the Programme Management Group and Steering Committee. We proposed to approach people via patient forums and clinical links, such as local tissue viability nurses and spinal injury units. We aimed to identify two service user members for each committee and prepare them for their roles via informal, supportive meetings with experienced team members. Meetings would be focused around the needs of the service users; both in terms of practical issues (e.g. timings, venue etc.) and the format of the meetings (e.g. language, chairing, agenda setting etc.).

Discrepancies between PPI activities undertaken and proposal funded

We did not establish service user membership of the Programme Management Group.

PPI activities undertaken that were not proposed

We have worked with service users in many other ways throughout the programme. The establishment of a PURPOSE PPI officer post enabled us to engage with service users and undertake more in depth PPI activities than set out in the funding application. For example:

- We have set up a service user research network which will continue to support research in this field beyond the life of PURPOSE.
- We have undertaken a series of meetings, workshops and consultations which focused on the service user perspective and have allowed input into all of the PURPOSE studies.
- We undertook an evaluation of PPI in the Severe Pressure Ulcer Study.
- We have involved service users in interpretation, dissemination and implementation of research findings.
- We have shared our learning and PPI methods with the tissue viability and PPI research communities.
- On-going support and mentorship has been offered to service users and development opportunities, such as conferences and training, have been provided where possible.

Pain studies

Summary of proposal funded

The pain work package proposed to determine the prevalence, type and severity of localised pressure ulcer pain in 'pressure areas' in patients with clinically assessed normal skin, erythema, superficial and severe pressure ulcers and explore the role of pain as an early predictor of Category 2 (or above) pressure ulcers. We planned: i) multicentre prevalence to determine the extent of pressure area related pain, nested within routine annual pressure ulcer prevalence audits in acute and community NHS Trusts and ii) a multi-centre prospective cohort study.

We estimated that we would require 4,000 hospital and 2,700 community patients for the prevalence survey, requiring us to piggy-back this work onto routine prevalence surveys in 4–5 acute and 2–3 community Trusts, and 340 patients for the prospective cohort study (based upon a model including 8 factors and an incidence rate of 25%).

Discrepancies between research undertaken and proposal funded

Prevalence: we revised our sample size estimates in response to Board comments and planned to undertake nested prevalence in a minimum of 2 acute and 2 community NHS Trusts with an expected sample size of 2,000 hospital and 6,000 community patients. However, the community nursing caseloads estimated by the community trusts at the grant application stage were inflated and our original plan assumed that the community prevalence methodology was similar to long-standing and well established acute hospital methods where nurses undertake a comprehensive skin assessment of each patient. This was not the case for one of the Trusts, with the two participating community Trusts using different case finding methods. This together with the scale of the data collection task in the community setting led to an adaptation of the original plan as follows: a) the community and acute prevalence studies were conducted and analysed separately, b) the community pain prevalence estimates included only those patients with pressure ulcers and c) the total survey population was 5180.

Prospective cohort study: in the grant application we had planned to recruit patients into the cohort study from the prevalence surveys. In practice this was not practical due to the organisational demands of Trust-wide pressure ulcer prevalence audits. We amended the sample size estimate to 632 in response to Board comments, with the addition of analgesic use as a risk factor in the planned model and a reduced incidence rate (model including nine factors and an incidence rate of 15%). We planned to undertake additional exploratory analyses to: i) assess the relationship between pain as measured by the two assessment methods (numerical rating scale and LANSS) and pressure ulcer development and ii) assess the relationship between changes in pain over time and the time to pressure ulcer development by treating pain as a time-dependent co-variate in a Cox proportional hazards model. This secondary analysis has not yet been undertaken.

Research undertaken that was not proposed

Prevalence: we undertook a sub-study comparing community pressure ulcer case finding methods.

Cohort analysis: In the grant application we proposed one multi-variable model using logistic regression. We undertook four analyses including the *a priori* logistic regression along with an over-dispersion logistic regression model and an Accelerated Failure Time model conducted at a patient level, and a multi-level regression model for analysis conducted at a skin site level.

Severe pressure ulcer study

Summary of proposal funded

The work package had two objectives, namely, (1) identify individual and organisational factors which contribute to the development of severe pressure ulcers, and, (2) develop a critical incident/adult neglect methodology for their review. A retrospective case study design was proposed, based on the retrospective review of the events leading to patients developing severe pressure ulcers. The study would draw on the methods used by Perrow (1999) and Vaughan (1996), both of whom pieced together accounts of major accidents from a range of sources, including documents and interviews with people who had been present when the accidents occurred. Patients would be identified via critical incident and adult protection referrals, and then purposively sampled, in order to maximise the range of patient and service characteristics. Competing explanations for the development of severe pressure ulcers would be evaluated using Yin's 'elimination of hypotheses' method (2008).

The results would be fed back to local NHS teams responsible for critical incidents and for adult protection issues. It was envisaged that organisational risk factors, identified in this study, would be integrated with patient risk factors (in Study 3), and integrated into a single Minimum Data Set. A critical incident/adult neglect review protocol would be developed. Implementation would involve pilot work at two local sites, and then roll out to other participating centres. Study recommendations would be more widely disseminated.

Discrepancies between research undertaken and proposal funded

The only significant discrepancy concerns the identification of organisational risk factors, and the integration of those risk factors with the Minimum Data Set in Study 3. The study did not identify organisational risk factors that could be integrated in the manner originally envisaged. However, the findings did inform the design of the Risk Assessment Framework and which incorporated decision pathways which make a clear distinction between patients 'at risk' and those with an existing pressure ulcer who require secondary prevention and treatment, with escalation of interventions to prevent deterioration in existing pressure ulcers.

Research undertaken that was not proposed

A PPI led workshop was undertaken, where members of PURSUN UK were invited to contribute to the interpretation of some of the study findings. The workshop included video and role play to make the interpretation process engaging and accessible for service users with little or no experience of data analysis and interpretation.

References

Perrow C. *Normal Accidents*. New edition ed. Princeton: Princeton University Press; 1999.

Vaughan D. *The Challenger Launch Decision*. Chicago: University of Chicago Press; 1996.

Yin R. *Case Study Research: Design and Methods*. London: Sage; 2008.

Risk assessment

Summary of proposal funded

The risk assessment work package proposed to agree a pressure ulcer risk factor Minimum Data Set and use to underpin the development, implementation and evaluation of an evidence-based Risk Assessment Framework including safety flagging to guide decision making about risk of superficial pressure ulcers and risk of progression to severe pressure ulcers. The Risk Assessment Framework would adopt a stepwise approach with basic screening questions to quickly distinguish patients who are clearly not at risk and those who require more detailed risk assessment and would enable meaningful assessment and documentation of risk (incorporating anticipated patient need).

The proposal outlined work to update the pressure ulcer risk factor systematic review and using this along with the results from the severe pressure ulcer study and the pain studies, undertake a consensus study to agree a patient level risk factor Minimum Data Set. Using the Minimum Data Set we would go on to develop the Risk Assessment Framework and pilot, evaluate and implement the tool.

Discrepancies between research undertaken and proposal funded

In the original proposal the implementation and evaluation element of the Risk Assessment Framework development involved preliminary pilot work in one acute and one community trust with roll-out to other participating centres: the intended strategies included multi-disciplinary working groups, local guideline development, engagement of opinion leaders and incorporation into routine assessment/record keeping processes and the delivery of a package to support training and competency assessment in practice. Feedback from the local implementation teams would be used to refine the Risk Assessment Framework with ongoing consultation by the expert group. The intended evaluation included assessment of reliability (inter-rater and test re-test), face and content validity (assessed by local multi-disciplinary groups), compliance (via planned prevalence audits) and acceptability (through qualitative interviews with clinically based nursing staff).

The research actually undertaken provided a more structured approach, focussing on the evaluation and improvement of the Risk Assessment Framework to facilitate long-term implementation. Following the systematic review and the consensus study a pre-test with clinical nurses was undertaken to assess and improve the acceptability usability, format, design, clarity, comprehension, language and data completeness of the Risk Assessment Framework. This was considered an important and logical step in the tools development as it allowed improvements to be made prior to clinical evaluation. The clinical evaluation was undertaken in four acute and four community NHS Trusts and incorporated tissue viability nurses/research nurses and ward/community nurses using the Risk Assessment Framework with patients in a field test study. This allowed evaluation of the Risk Assessment Framework in relation to its inter-rater and test re-test reliability, convergent and known groups validity, data completeness and clinical usability. The more structured emphasis on the evaluation and improvement of the Risk Assessment Framework in the delivered studies of the programme will facilitate long-term implementation of the Risk Assessment Framework into routine NHS care.

Research undertaken that was not proposed

- We gained additional funding from the World Universities Network to enable international membership to the multi-disciplinary expert group (two US, three Netherland, one Israel, and 11 UK) of the consensus study.
- We integrated the views of service users (via PURSUN UK) into the consensus study methodology to ensure the acceptability of proposed assessment elements for patients was considered.
- Following on from the consensus study we undertook an additional piece of work to develop a new conceptual framework and theoretical causal pathway for pressure ulcer development. This allowed us to bridge the gap between the epidemiological, physiological and biomechanical evidence.

Pressure ulcer quality of life

Summary of proposal funded

The work package proposed to develop and validate a psychometrically rigorous, patient-reported outcome (PRO) measure of HRQoL in patients with pressure ulcers (the PU-QOL instrument) that is reliable and valid, and suitable for use in the NHS. We planned to: i) develop a conceptual framework based on evidence from a systematic review of the PRO and HRQoL literatures, qualitative interviews with patients, and expert opinion; ii) produce a draft questionnaire and pre-test it using cognitive interviewing and a computerised appraisal tool; the Questionnaire Understanding Aid (QUAID); and iii) evaluate the psychometric properties of the PU-QOL in two-stage field testing using both modern and traditional psychometrics, including: a preliminary field test (item reduction) to identify items with poor psychometric properties for possible elimination and identify subscales, and a final (psychometric evaluation) field test to evaluate the reliability and validity of the item-reduced version of the PU-QOL instrument.

Discrepancies between research undertaken and proposal funded

We developed a researcher administered instrument and not a self-complete questionniare following an optimal mode-of-administration sub-study.

For the pre-test anaysis, we proposed to use the QUAID to analyse the cognitive interview data. However, instead we used a coding tool, the Quality Appraisal System (QAS-99), that focuses on the cognitive demands required for answering a question and potential item characteristics that may lead to response error. We also used Rasch analysis to examine the PU-QOL instruments' response options, appropriateness of the item series, and biases due to question ordering and compared the cognitive interview and Rasch analysis findings to guide decision-making about further revisions to items and questionnaire design/layout.

For the psychometric evaluation phase, we proposed to use factor analysis, however instead we used Rasch analysis to investigate hypothesised scales. Rasch measurement theory provides a formal method of testing the degree to which rigorous measurement is achieved by rating scales, therefore use of factor analysis to determine scale structure was not deemed necessary.

Research undertaken that was not proposed

- We undertook a sub-study to investigate optimal mode-of-administration for the PU-QOL instrument (between patient self-complete and interviewer-administration).
- We completed two additional systematic reviews: 1) to explore content from existing chronic wound HRQoL outcome measures and 2) to explore patient reports of pressure ulcer-related pain.
- We undertook an additional preliminary Rasch analysis on pre-test data to investigate PU-QOLs' response options, appropriateness of the item series, and biases due to question ordering prior to large scale field testing.

Pressure ulcer cost utility

Summary of proposal funded

This work package proposed to assess the value patients place on the prevention and cure of pressure ulcers and to develop a pressure ulcer-specific health utility measure. We planned to: identify items for inclusion in the utility index from the PU-QOL instrument using Rasch measurement theory; undertake a valuation survey involving patients using a choice-based approach (the standard gamble); use modelling techniques to derive and test the utility algorithm.

Discrepancies between research undertaken and proposal funded

There were two main discrepancies between the research proposed and that undertaken: we used Time Trade Off and not Standard Gamble to elicit preferences; and the valuation exercise was conducted with the general population rather than patients. These changes were in part driven by updated guidance on technology appraisal by the National Institute for Health and Clinical Excellence which reaffirmed two key recommendations for valuation studies; that valuations should come from the general population and not patients with the condition; and that the valuation method should match that employed in the valuation of the EQ-5D (i.e. Time Trade Off). It also became apparent that a valuation survey would be particularly challenging in this patient group given that many were quite poorly, frail and elderly. The latter fact presented both practical and methodological issues.

Research undertaken that was not proposed

The validation study (study B) was additional research that was not originally proposed. This was felt necessary because the PU-QOL instrument incorporated an 'attribution' question format and this represented a methodological challenge to the generation of the utility index. We, therefore, undertook a validation sub-study which involved a patient survey ($n = 100$) with completion of a revised (attribution free) PU-QOL along with the EQ-5D allowing us to verify the item selection process and also allowing a psychometric assessment of the PUQOL-UI. These analyses enhance the overall body of work and the survey data will present future methodological research opportunities.

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